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Biosecurity in UK research laboratories

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Summary

Possessing the high containment laboratories necessary to tackle existing and emergent infectious diseases of both humans and animals is of the upmost importance to the UK. It was ironic that a leak from such a laboratory at Pirbright in 2007 is the most recent demonstration of how devastating infectious disease can be. It is critical that such an incident does not happen again. This Report outlines a number of shortcomings in the way capacity for high containment research is provided and highlights where the Government should take action.

Primarily, we conclude that there is a striking lack of co-ordination between organisations who sponsor and run high containment laboratories. No one organisation or Minister has the remit to maintain a strategic overview of capacity and to co-ordinate these laboratories. There is significant potential for collaboration at a more formal level to assess what facilities are available and make best use of them, identifying any gaps. There is also room for more co-ordination and standardisation of the vetting and training of staff working in this area.

We have identified shortcomings in the funding of high containment facilities, particularly for the significant cost of ongoing maintenance. This must be rectified to ensure the incident at Pirbright is not repeated. A number of high containment laboratories have been neglected and the funding situation is uncertain. The Government must ensure that dependable funding is provided to maintain such facilities safely.

The new regulatory framework to be introduced in the wake of the Pirbright outbreak is a positive step and should provide a framework in which those operating high containment facilities, given sufficient resources, should be able to continue their work to protect the UK from the threat of infectious disease.

1 Introduction

The threat from infectious disease

1. Dangerous pathogens[1] of humans, animals and plants represent a major threat to public health and the economy. The impact of infectious disease in animals was demonstrated by the outbreaks of Foot and Mouth Disease Virus (FMDV) in 2001 and 2007. An unexpected outbreak of human disease could have similarly devastating consequences. The possibility of a human influenza pandemic has led the Government to formulate a national framework to plan for such an eventuality, describing it as "a real and daunting challenge to the economic and social wellbeing of any country and a serious risk to the health of its population".[2]

2. To combat the threat of known, emerging and re-emerging infectious diseases, scientists are engaged in two types of work. First, research is carried out to increase understanding of known dangerous pathogens and how to detect and treat them, for example using vaccines. Secondly, samples from suspected cases are processed in diagnostic laboratories for detection of pathogens. During an outbreak of an infectious disease, a rapid expansion of such diagnostic capacity is required to identify cases.

3. Pathogens evolve constantly. For example, 38 apparently new species of human pathogen have been recognised in the last 25 years.[3] Climate change is likely to affect the emergence and characteristics of infectious disease and their transmission in the UK.[4] Globalisation and the ease of international travel allow infections to spread rapidly.

4. In addition to the threat from natural infections, dangerous pathogens can be weaponised and the security services are alert to the potential for malicious use of pathogenic material as a terrorist weapon, especially in the wake of the use of anthrax for this purpose in the USA in 2001.[5] The recent Government Foresight project on the detection and identification of infectious diseases demonstrated the threat they pose and also provided a comprehensive analysis of possible future risks.[6]

Managing risk

5. Dangerous pathogens are handled in containment laboratories to reduce the risk of release into the environment and also to protect the handler. The precautions taken depend upon the properties of the pathogens in question, the potential severity of disease

1 A pathogen is a disease causing agent, for example a virus or bacterium

2 *Pandemic Flu, A national framework for responding to an influenza pandemic*, Cabinet Office and Department of Health, November 2007, p 5, www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_080734

3 Office of Science and Innovation, *Foresight: Infectious Diseases: preparing for the future, Future Threats*, p 25, www.foresight.gov.uk/Drumbeat/Infectious%20Diseases/t1.pdf

4 Ev 107, 164; Q 102, Office of Science and Innovation, *Foresight: Infectious Diseases: preparing for the future,* T7.1: Climate change and diseases of plants, animals and humans: an overview

5 USGAO, High-containment biosafety laboratories: *Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, October 2007, p 1

6 Office of Science and Innovation*, Foresight: Infectious Diseases: preparing for the future, Future Threats*

and the countermeasures available. Despite the precautions taken, there have been incidents where pathogens have escaped laboratory containment, often as a result of a breakdown in procedure. In 1978 the last fatal case of smallpox in the UK occurred in Birmingham after the virus escaped from a laboratory.[7] The 2007 UK outbreak of FMDV almost certainly originated at a site handling the virus at Pirbright, Surrey.[8]

Background to our inquiry

6. The outbreak of FMDV at Pirbright in 2007 brought the issue of biosecurity to the top of the political agenda. In the aftermath of the outbreak a number of reports were commissioned. The Health and Safety Executive (HSE) led an investigation into any potential breach of biosecurity at the site, and an "Independent Review of the safety of UK facilities handling foot-and-mouth disease virus", chaired by Professor Brian Spratt, published more detailed findings, some of which relied on the investigations carried out by the HSE. The Spratt report contained the caveat that "the amount of hard science that could be applied to our investigation of the source of the outbreak was very limited … identifying the source of an outbreak of this kind with any certainty is always likely to be inconclusive, unless some gross and obvious breakdown in a safety critical feature has occurred".[9] Both reports concluded that release of FMDV through defective effluent pipes was the most probable source of the outbreak. The most likely explanation is that, after release from the drainage system, live FMDV contaminated soil/materials on the Pirbright site which were transferred by vehicles to farms in the vicinity.[10] The source of the virus could not be established conclusively given that the strain in question had been handled by both the Institute for Animal Health (IAH) and a private company Merial, who share the site, although the virus was used in much larger quantities by the latter.[11]

7. Following these reports on the cause of the outbreak, two additional pieces of work were commissioned by the Government. First, Sir Bill Callaghan was asked to review the regulatory framework for human and animal pathogens,[12] and secondly the Prime Minister and Secretary of State for Environment, Food and Rural Affairs commissioned Dr Iain Anderson to lead an independent review of the lessons learned from the response to the 2007 FMDV outbreak.[13]

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7 Shooter RA, *Report of the Investigation into the cause of the 1978 Birmingham Smallpox Occurrence*, London: Her Majesty's Stationary Office, 1980

8 Health and Safety Executive, *Final Report on potential breaches of biosecurity at the Pirbright site* 2007, 31 August 2007, p2, www.hse.gov.uk/news/archive/07aug/finalreport.pdf; Professor Brian Spratt and review team, *Independent Review of the safety of UK facilities handing foot-and-mouth disease virus*, August 2007, p 5

9 Professor Brian Spratt and review team, *Independent Review of the safety of UK facilities handling foot-and-mouth disease virus*, August 2007, p 15, www.defra.gov.uk/footandmouth/investigations/pdf/spratt_final.pdf

10 Professor Brian Spratt and review team, *Independent Review of the safety of UK facilities handling foot-and-mouth disease virus*, August 2007, pp 43-54; Health and Safety Executive, *Final Report on potential breaches of biosecurity at the Pirbright site* 2007, 31 August 2007, pp 44-46

11 Professor Brian Spratt and review team, *Independent Review of the safety of UK facilities handling foot-and-mouth disease virus*, August 2007, pp 25-27; Health and Safety Executive, *Final Report on potential breaches of biosecurity at the Pirbright site* 2007, 31 August 2007, pp 16-19.

12 Sir Bill Callaghan, *A Review of the Regulatory Framework for Handling Animal Pathogens*, 13 December 2007, www.defra.gov.uk/animalh/diseases/fmd/pdf/callaghan-reviewreport071213.pdf

13 Dr Iain Anderson, *Foot and Mouth Disease 2007: A Review and Lessons Learned*, 11 March 2008, http://interactive.cabinetoffice.gov.uk/documents/fmd/fmd_2007_review.pdf

8. Our inquiry was not intended to be a re-run of the numerous inquiries that followed the FMDV outbreak. Instead, we sought to identify the generic lessons to be learnt from what happened, examining whether further action is necessary to prevent a similar outbreak of infectious disease from occurring again in the UK. Issues surrounding biosecurity in the UK continue to generate interest. The future of Pirbright is yet to be fully resolved since its redevelopment has run significantly over budget.[14] The possibility that the proposed new UK Centre for Medical Research and Innovation (UKCMRI) in central London will handle dangerous pathogens has received significant public attention.[15]

9. It is essential to protect the economy and the health of human and animals by ensuring that appropriate biorisk management occurs at high containment facilities and that they are managed within an appropriate regulatory framework. Safeguards should be proportionate and risk-based to avoid unnecessarily restricting research. High-containment facilities should be resourced sufficiently to be well-maintained which means that funding must be available on a stable, dependable basis. Given the high cost of running high containment facilities, it is important that the UK makes best use of those that currently exist and any duplication is avoided. Clearly defined plans are necessary for immediate implementation in the event of further disease outbreaks. The supply, training and vetting of staff in this area is vital for maintaining the UK's capacity to undertake this vital research. At present the UK enjoys a high international profile in the field of infectious disease[16] which it is essential to maintain. These are factors which underpinned our examination of policy on biosecurity in UK research laboratories.

Our inquiry

Terms of reference

10. We announced our inquiry on 6 December 2007. Those submitting evidence were invited to address the following points:

- the current capacity for research on dangerous pathogenic material in the UK and the capability to conduct research on the causative agents of disease that may emerge at a future time;
- the state of biological containment facilities in the UK;
- laboratory inspection regimes and the rationale and practicalities of the licensing system;
- biosafety training provision for staff working in containment facilities;
- the maintenance and recording practices surrounding the storage and transportation of dangerous pathogens;

14 Ev 108

15 Terror fears over disease laboratory at King's Cross, *The Evening Standard*, 23 April 2008, p 24; Coming soon?: A medical research lab is planned for the heart of London. Is it safe to house a facility dealing with deadly diseases in a large urban population? *The Guardian*, 22 April 2008, p 1 Education.

16 Ev 50, 68, 81, 105, 114

- measures implemented when pathogenic material cannot be accounted for; and
- the role of universities in overseeing security clearance for research students working with dangerous pathogens.[17]

Specialist advisers

11. We appointed two specialist advisers to this inquiry:

- Professor Joe Brownlie, Professor of Veterinary Pathology (and former Head), Department of Pathology & Infectious Diseases, Royal Veterinary College; and
- Professor Colin Howard, Vice-Principal for Strategic Development and Professor of Veterinary Microbiology, Royal Veterinary College. Formerly Professor of Virology at the London School of Hygiene and Tropical Medicine. Member of the Advisory Committee on Dangerous Pathogens.

12. We are grateful to the advisers for their expert advice throughout the course of this inquiry.

Conduct of inquiry

13. We received 45 written memoranda and held three oral evidence sessions, hearing from a wide range of stakeholders. The cross-cutting nature of this subject was underlined by the fact that the Government submission combined contributions from eight departments: Home Office, Department for Transport, HSE as a sponsored body of the Department for Work and Pensions, Department of Health, Department for Innovation, Universities and Skills (DIUS), Foreign and Commonwealth Office (FCO), Department for Environment, Food and Rural Affairs (Defra) and Ministry of Defence.

14. The inquiry began with an informal seminar with Sir Bill Callaghan, former chair of Health and Safety Commission and Chairman of the review of the regulatory framework for handling animal pathogens, Professor George Griffin, Chair of the Advisory Committee on Dangerous Pathogens (ACDP), Professor Tony Minson, Head of Virology, University of Cambridge and Pro-vice Chancellor for resources and planning and Dr Sushil K Sharma, Assistant Director, Center for Technology and Engineering, U.S. Government Accountability Office (GAO). In addition, we undertook a number of visits in connection with the inquiry. In Germany we visited the Robert Koch Institute in Berlin, the Friedrich Löeffler Institute on the Isle of Reims and the Federal Agency for Occupational Safety and Medicine (BAUA). On a visit to Pirbright, we visited both the IAH and Merial. Finally, we visited the Health Protection Agency (HPA) Centre for Emergency Preparedness and Response and DSTL at Porton Down. We are grateful to all those we met at these facilities.

17 Press release, 6 December 2007, http://www.parliament.uk/parliamentary_committees/ius/ius_061207a.cfm

Definition of terms

15. There is some confusion over the use of terms that refer to the strategies to ensure dangerous pathogens are successfully contained. Our inquiry refers to 'biosecurity'. The HSE also used this term in its report on the outbreak of FMDV at Pirbright, although the report noted that "there is no accepted definition of 'biosecurity'," and determined that for its purposes:

> The term will cover the implementation of a combination of containment measures and working practices, supplemented by management controls, to prevent the inadvertent exposure of susceptible species to biological agents and their distribution in the wider environment. In practice, this requires a comprehensive system of both physical and procedural controls to minimise potential release of a pathogen along with suitable arrangements to minimise its subsequent spread.[18]

16. Some submissions to our inquiry have differentiated between biosecurity and biosafety as means of preventing what is unauthorised as opposed to unintentional.[19] In their submission, Research Councils UK (RCUK) outline World Health Organisation definitions of the terms:

> Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins or their accidental release.
>
> Laboratory biosecurity describes the protection control and accountability for valuable biological materials (including pathogens and toxins) within laboratories in order to prevent their unauthorised access, loss, theft, misuse, diversion or intentional release.[20]

17. We also use the term 'biorisk' in this report to encompass both biosafety and biosecurity. Dr Bernd Haas of the Friedrich Loeffler Institute, Germany provided the following definition of biorisk:

> Combination of the likelihood of the occurrence of an adverse event involving exposure to biological agents and toxins and the consequence (in terms of accidental infection, toxicity or allergy or unauthorised access, loss, theft, misuse, diversion or release of biological agents or valuable biological material) of such an exposure.

18 Health and Safety Executive, *Final Report on potential breaches of biosecurity at the Pirbright site 2007*, 31 August 2007, p 4.

19 Ev 73, 90, 121, 151

20 Ev 90, referring to World Health Organisation, Biorisk Management – Laboratory Biosecurity guidance, September 2006, pp iii-iv

2 The regulatory framework

Current framework

18. The regulatory frameworks governing the use of dangerous pathogens are based on the categorisation of pathogens into four groups. Pathogens that are handled at Containment Level (CL) 1 pose least risk whilst those at CL4 present the greatest risk. Dangerous pathogens are those classified CL3 or CL4, although CL4 containment is significantly more complex and expensive than CL3 containment.

19. Currently a number of parallel sets of regulations and systems of categorisation are in operation in relation to dangerous pathogens:[21]

- The Specified Animal Pathogens Order 1998 (SAPO) regulates the use of animal pathogens and was, until recently, administered by Defra in England, the Scottish Executive and the National Assembly for Wales. Following the Callaghan report (see below), HSE is now the inspection and enforcement body under SAPO across Great Britain. SAPO is a licensing system where the licence specifies the conditions under which the pathogen can be handled, following an inspection of the laboratory and close examination of supporting documentation. Licences are usually valid for 5 years. Specified animal pathogens are classified into four categories (SAPO1–4);

- The Control of Substances Hazardous to Health Regulations 2002 (COSHH) regulations are wide-ranging, and are not devoted to regulation of dangerous pathogens. HSE is the competent authority under COSHH across the UK. Like SAPO, COSHH classifies pathogens into hazard groups 1–4, based on the threat to human health as detailed in the 'Approved List of Biological Agents',[22] drawn up in consultation with the ACDP, an independent committee which advises the HSE, DH and Defra as well as the Devolved Administrations on all aspects of exposure to pathogens. ACDP is serviced by a joint secretariat (HSE, Defra, and the HPA).[23] CL assignments under COSHH are often referred to as ACDP 1–4. In contrast to SAPO, COSHH regulations require only that work is notified to HSE at least 20 days before it begins, although the HSE can request further information following notification;

- The Genetically Modified Organisms (Contained Use) Regulations 2000 GMO(CU) regulates pathogens which have been genetically modified and assigns a class of containment based on a risk assessment. Requirements differ from COSHH since the regulations are designed to protect the environment as well as the worker. For pathogens falling into class 2, 3 or 4, notification (including a risk assessment) is required and at class 3 or 4, permission is required before work commences. Responsibility for GMO(CU) is devolved in Scotland but not in Wales, so that the HSE and Defra in England and Wales and the HSE and the Scottish Executive in Scotland are the competent authorities;

21 Ev 51-61

22 ACDP, *The Approved List of Biological Agents*, 2004, www.hse.gov.uk/pubns/misc208.pdf

23 Ev 95

- Part 7 of the Anti-terrorism Crime and Security Act 2001 (ATCSA) applies across the UK and allows the police to impose security measures in those laboratories handling pathogens and toxins on a list in Schedule 5 of the Act, use of which must be notified. The Act covers around 400 laboratories in the UK. ATCSA is implemented by the National Counter-Terrorism Security Office (NaCTSO), a national police unit, which provides policy advice and police training.

We are aware that similarly complex regulatory systems are in place around the world, for example in Germany where the involvement of regional authorities adds an extra dimension.[24]

20. Pathogens may be categorised differently under two or more systems, for example SAPO4/ACDP3, and requirements for the same level of containment can differ, for example between SAPO4 and ACDP4. In addition, laboratories operating at a particular containment level are not identical. The containment measures and standard operating procedures will depend on the pathogen being used but also the protocols. Diagnostic and research laboratories present different risks as a result of the nature of the work. CL4 laboratories can vary widely in their capabilities and capacity as we discuss in detail below. In recognition of this, derogations are often awarded;[25] for example, Dr Paul Logan of the HSE explained that:

> if you are working with prion agents which are not transmitted by the airborne route and are not susceptible to fumigation, you may have a level three laboratory that does not include those measures. You can in the consent have a derogation for those particular measures. That is why it is a strength. It gets people to think about what they are going to be doing and put that in a consent application.[26]

The Callaghan review

Criticisms of the existing regulatory framework

21. In the wake of the FMDV outbreak at Pirbright, the Secretary of State for Environment, Food and Rural Affairs commissioned a review from Sir Bill Callaghan of the regulatory framework governing the handling of animal pathogens and Defra's role as regulator under SAPO. This further review was one of the recommendations of the Spratt Review which highlighted the potential conflict of interest that existed at Pirbright where Defra was both a customer, and the regulator under SAPO.[27] Callaghan identified the existing regulations as "complex and disjointed"[28] (a conclusion with which others agree)[29] and described the existing regulations relating to human and animal pathogens as having "differing regulatory philosophies and practices, and different levels and types of

24 Ev 127-128

25 Ev 63

26 Q 83

27 Professor Brian Spratt and review team, Independent Review of the safety of UK facilities handing foot-and-mouth disease virus, August 2007, p 58

28 Q 9

29 Ev 54, 82, 90

inspection, enforcement and sanctions."[30] The SAPO regime received particular criticism. The resources allocated to regulation were limited, with under half the time of one Defra veterinary official to cover all the SAPO4 laboratories. Enforcement of the regulations was the responsibility of trading standards officials who, according to the Callaghan review, have never used these powers.[31] Callaghan concluded that:

> Taking together the potential conflict of interest and our concerns about Defra's technical expertise, and noting the low level of resource Defra has committed to an area that clearly demands a high level of expertise across a range of technical areas, we conclude that Defra is not in a position to act as an independent regulator of laboratories handling animal pathogens.[32]

22. Callaghan was not alone in identifying failings of the existing regulatory system. Iain Anderson's review of the 2007 FMDV outbreak concluded that it had highlighted "weaknesses in the total regulatory system, not the failure of one individual. The Defra regulator, for example, was doing his best with limited resources."[33] He added that "Defra's regulatory regime was insufficiently robust given the level of risks on the site".[34] Defra itself was already considering changes to the SAPO regime and whether a move to a single regulator was desirable.[35]

23. Callaghan was clear that at Pirbright "in the face of the published correspondence from Merial about the state of the drains … an independent regulator such as HSE would have ... taken steps to ensure the drains were functioning properly."[36]

24. The failings of the regulator therefore appear to have been a contributory factor to the FMDV outbreak. However, when challenged by us Defra officials would not accept that faults in regulation were behind the outbreak. Dr Nick Coulson of Defra told us that:

> There were regulatory issues that we were aware of at Pirbright and we were working with them … We accept that the regulatory system can be improved. We do not accept that the regulatory system was responsible for the release from Pirbright … We are responsible for issuing licences in respect of the site but the responsibility for biosecurity on the site is for the management of the site.[37]

Callaghan's recommendations

25. Sir Bill Callaghan suggested that there should be a new, unified regulatory framework for human and animal pathogens based on risk-assessment with a common set of containment measures developed by ACDP and that the HSE should be the competent

30 Sir Bill Callaghan, *A Review of the Regulatory Framework for Handling Animal Pathogens*, 13 December 2007, p 20

31 Q17, Sir Bill Callaghan, *A Review of the Regulatory Framework for Handling Animal Pathogens*, 13 December 2007, p 10

32 Sir Bill Callaghan, *A Review of the Regulatory Framework for Handling Animal Pathogens*, 13 December 2007, p 19

33 Dr Iain Anderson, *Foot and Mouth Disease 2007: A Review and Lessons Learned*, 11 March 2008, p 100

34 *Ibid.*

35 Qq 3, 73

36 Q 5

37 Qq 74-5

authority. He recommended that the framework be in place by the end of 2008 and that in the meantime the HSE should take responsibility for inspection and enforcement under SAPO as part of a series of phased changes to be completed by April 2008.[38] The Government accepted all the recommendations made in the review.[39] Support for the findings was widespread in the evidence we received.[40]

Implementation of the Callaghan review

26. We are encouraged that the timetable for the proposed new framework is currently being met. On 28th April 2008 the HSE became the enforcement and inspection body under a revised SAPO. The process of developing the new single regulatory framework has also begun.[41] The ACDP met on 5th February 2008 to begin work on a common set of containment measure to apply to animal and human pathogens.[42]

27. Consolidating three different sets of regulations into a single regulatory framework will not be easy given the different bases on which they currently operate.[43] Sir Bill Callaghan pointed out that COSHH places responsibilities on *employers* to control risk, SAPO regulates the possession of controlled pathogens by *individuals* and GMO(CU) requires a *person carrying out an activity* to do so safely and to carry out a risk assessment.[44]

28. One of Callaghan's key recommendations was that the new regulatory framework be based on risk assessment. As described above, SAPO is a licensing regime, work under COSHH requires notification and GMO(CU) requires permission.[45] In other countries a mixture of systems operate, with the Netherlands and Canada operating a permit system and Switzerland a licensing system.[46] Callaghan described licensing regimes as "more rigid" and commented that under SAPO the regulator lacked sanctions except the removal of the licence.[47] Others agreed, with the HSE considering this an endorsement that "our risk assessment approach is seen as a modern way of regulating rather than issuing licenses."[48] However, this view was not universal and other evidence suggested that it is possible for a licensing system to work well.[49] Andrew Thompson, Biological Safety Officer at Oxford University asserted that with licensing "the process is, if anything, more vigorous and more controlled than that undertaken for human (ACDP) pathogens."[50] Robert Osborne, Biological Safety Adviser at Glasgow University argued that in the short term a notification

38 Sir Bill Callaghan, A Review of the Regulatory Framework for Handling Animal Pathogens, 13 December 2007, pp 6-28

39 HC Deb, 13 December 2007, col 52WS

40 Ev 63, 66, 82, 91, 109, 115, 123, 152; Qq 72, 74, 173-178, 231, 244

41 HC Deb, 29 April 2008, col 6WS

42 Ev 95

43 Qq 14, 85

44 Sir Bill Callaghan, *A Review of the Regulatory Framework for Handling Animal Pathogens*, 13 December 2007, p 8

45 Ev 55-56, 160-161, 163

46 Ev 130, 133, 147

47 Qq 7-8

48 Qq 82, 182

49 Ev 69, 73, 103

50 Ev 73

regime could allow poor practice and recommended that permission be required for work to commence.[51]

29. Lord McKenzie, the Minister with responsibility for the HSE, told us that it is still to be decided whether the new regulatory framework will be a permissioning or notification regime but that a licensing regime is not being considered.[52] Sir Bill Callaghan was very clear that "the model we have for the single regulatory framework is based on the GMO (Contained Use) Regulations,"[53] where permission is required to start work at CL3 or CL4. We note that at present a similar system is operated informally by the HSE under COSHH; even though the approval of the regulator is not strictly required, in practice the HSE told us that they:

> send an acknowledgement of receipt with statement that they will receive a further letter in due course to confirm that you may begin work with the agent(s). Once HSE are satisfied they will send a second letter to approve the work.[54]

30. As described, the regulations that govern work with dangerous pathogens are devolved in a complex pattern with multiple agencies as a competent authority, for example under GMO(CU).[55] Dr Paul Logan of the HSE told us that devolution complicated the issue but that:

> A laboratory handling a particular agent should be working to the same standards whether it is north of the border or south of the border, or in Wales. The buy in from the Scottish Government and the Welsh Government now is that they welcomed the recommendations in Sir Bill Callaghan's report and are participating in the discussions.[56]

It should be noted that the systems in Germany and Switzerland operate to a large extent at a local rather than federal level without any apparent problems.[57]

31. Witnesses stressed to us that it will be important in developing the new framework to focus on reducing, not creating complexity.[58] The Wellcome Trust suggested that

> a single focal point of contact between a research institution and the cohort of regulators would be helpful. This function could sit within the Health and Safety Executive, and could operate regionally so that it acts as a conduit between research institutions and the relevant authorities responsible for regulatory oversight in that location. At the local level, such a system would help to build integrated arrangements between institutions and the various regulators. Strategically, at the

51 Ev 79

52 Qq 314-315

53 Q 6

54 Ev 163

55 Ev 56

56 Qq 94-97

57 Ev 127-128, 147

58 Ev 82, 90, 156; Qq 183-185

national level, it could assist the various regulators to have a clearer picture of, and to develop enhanced responses to, biosecurity risks.[59]

However, it is possible to oversimplify the system inappropriately. Some areas require expertise that the HSE will not have available. For example, counter-terrorism and security needs to be enforced by specialists (Home Office, NACTSO etc). In common with other witnesses,[60] Dr Paul Logan's view was that for the HSE to be "working closely together [with the security services] is probably the best answer, rather than trying to take on those functions."[61]

32. **We support the conclusions reached by Sir Bill Callaghan and believe that a single, unified regulatory framework for human and animal pathogens based on risk assessment is the appropriate step forward. We urge the Government to ensure that regulation of work on dangerous pathogens is simplified as far as is practicable with the minimum number of bodies involved, although it may be appropriate for some specialist areas such as counter-terrorist inspection to be administered separately in accordance with the common framework. The Government should co-operate with the devolved administrations to ensure that a similarly high standard of regulation occurs across the UK.**

33. **We recommend that the new unified regulatory framework be a permissioning regime such that approval by the regulator should be required before work can start where an application for work at CL3 or CL4 has been submitted.**

Categorisation of pathogens and containment measures

34. The categorisation of pathogens is regularly reviewed by ACDP to account for changes in drug resistance, virulence etc.[62] In the wake of the Callaghan review, as part of the new unified regulatory framework, ACDP has been tasked with formulating a common set of containment measures for human and animal pathogens.

35. Whilst many dangerous pathogens are zoonotic and infect humans and animals, it may be difficult to formulate a common set of containment measures appropriate for human pathogens and those animal pathogens at the extreme of the spectrum (e.g FMDV) which pose no danger to humans and are therefore classified as SAPO4/ACDP1. Under current SAPO4 containment human operators often come into direct contact with the agent. Callaghan's view was that "if you say something is level 1 it sounds as if it is not really important."[63] His review expressed concern that:

59 Ev 82

60 Qq 20, 309, 274-276

61 Q 103

62 Qq 23-28

63 Q 29

> Although in that case no harm would be caused to the workers themselves from the purely animal pathogens, we consider that this could lead to an increase in risk of contamination of the environment.[64]

Professor Griffin, chairman of the ACDP, suggested that "animal pathogens under SAPO will have tighter regulations than before."[65] In safety terms the benefits of such an approach are obvious. However, increasing the precautions required for work on pathogens such as FMDV may serve to deter scientists from carrying out such work and make it prohibitively expensive.

36. The Society of General Microbiology (SGM) expressed concern that some microbes previously handled in undergraduate practicals are now considered 'dangerous' and that overall too many pathogens are now defined as dangerous.[66] There is a danger that a lack of evidence-based risk assessment could lead to an inflation of the containment levels required for handling particular pathogens. Michael Stephens of the Institute of Safety in Technology and Research told us that:

> there is a real danger with this creep … that pathogens that are not truly Category 4 can creep into Category 4 and dilute the risk perception.[67]

Within a new, common regulatory framework for animal and human pathogens, risk assessment should determine the biorisk management strategy for containment laboratories.

37. **We support a common set of containment measures for animal and human pathogens and urge ACDP, in drawing up these measures, to protect the principles of evidence-based risk assessment. They should consider the implications for the viability of important research if unnecessary containment measures are imposed. We expect ACDP to maintain its regular review of required containment measures and the classifications of pathogens under the new framework.**

Transport of pathogens

38. The transport of dangerous pathogens falls outside the new unified regulatory framework, given that it has an international element and requires co-operation at this level. For the most part, those submitting evidence considered transport regulations to be adequate.[68] The Importation of Animal Pathogens Order 1980, as amended, prohibits import of pathogens from outside the EU without a licence from Defra, the Scottish Executive or Welsh Assembly. The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2007, enforced by the HSE, transpose international regulations originating at the UN and define two categories of infectious substances for which the transport conditions differ. The international air transport association also has its own transport regulations. In addition to the specific legislation on

64 Sir Bill Callaghan, *A Review of the Regulatory Framework for Handling Animal Pathogens*, 13 December 2007, p 13

65 Q 9

66 Ev 157

67 Qq 238-240

68 Ev 64, 73, 115, 123, 153

this issue, SAPO licences also stipulate transport conditions and COSHH requires notification to the HSE before CL4 pathogens are moved to another site. We received a suggestion that better contingency plans were needed for loss and damage of packages containing dangerous pathogens during transportation[69] and a warning that if transport of samples became prohibitively expensive, it would be detrimental to the essential exchange of samples, especially important in the work of Reference Laboratories.[70] The Department for Transport is currently reviewing the transport of dangerous goods, in particular Very High Consequence Dangerous Goods. This may present an opportunity, in the spirit of the Callaghan Review, to rationalise regulation in this area.

Gaps in the regulations

39. The development of a new unified regulatory framework also provides the opportunity to identify any gaps in the current regulations. Dr Paul Logan of the HSE told us that "the keeping of inventories is something that is quite often raised" and that this is becoming more commonplace.[71] Present legislation covering work on dangerous pathogens stipulates "secure storage". At CL4, organisms must only be stored within the laboratory, and fridges, freezers and storage containers should be kept locked. NaCTSO, through Counter-Terrorism Security Advisers (CTSAs), carry out security audits under ATCSA. However, this is another area which lacks clarity. SAPO licences require details to be kept of storage locations, quantities and disposal[72] but COSHH and GMO(CU) regulations do not. RCUK suggested a "single nationally accepted system for logging information on the storage of dangerous pathogens" and "a standard labelling system". They also pointed out that "there is no formal requirement, as for example for radioactive material, to account for missing pathogens".[73] However, other witnesses suggested that the quantitative recording of dangerous pathogens may not be practicable[74] and that there is a possibility that clearly identifying pathogenic material may make it more vulnerable to theft.[75] Professor Shirley of the IAH told us that ultimately, no system can completely protect from malicious behaviour.[76]

Responsibility for biosecurity

40. Whilst the regulatory system provides the framework within which dangerous pathogens can be handled, ultimately the responsibility for managing risk lies with those who manage the site.[77] The ACDP guidance for running containment level 4 facilities notes that:

69 Ev 99, 157

70 Ev 104, 115

71 Q 127

72 Ev 94

73 Ev 94

74 Ev 64, 80, 73, 104; Q 128

75 Ev 74

76 Q 237

77 Qq 14, 22, 56, 75, 86, 366; Ev 81

> Specific functions, such as carrying out risk assessments, may be delegated down the management chain but it should be remembered that responsibility for health and safety management cannot be delegated.[78]

41. A clear definition of where responsibility for biosecurity lies is vital and it is important on a site of shared ownership to identify 'the controlling mind' as in the principles of Health and Safety legislation.[79] The difficulties that can arise when this is not clear are starkly illustrated by the outbreak of FMDV at Pirbright, where a number of problems were identified with the complexity of the governance on the site and lack of communication between different parties.[80] The HSE highlighted that in general the situation is improving:

> When we do inspections we really have to tease out who is taking responsibility. What we find when we gather evidence is that more and more there will be high level agreements between for example a senior director of a charity and a senior director of a university.[81]

42. Witnesses emphasised the need for a strong safety culture to pervade all organisations using dangerous pathogens.[82] Biological safety officers/advisers (BSOs) are key to successful biorisk management. The ACDP guidelines emphasise that:

> The recruitment of a biological safety advisor (BSA) is pivotal in ensuring management are provided with sufficient information and advice to ensure risks related to biological agents are either controlled or prevented.[83]

There is widespread support for a more high profile role for BSOs and for giving them professional status.[84] The Wellcome Trust advocated that the role of BSOs could be built into the regulatory framework.[85]

43. **There should be complete clarity over who is responsible for biosecurity, especially on a site of mixed ownership or sponsorship such as at Pirbright. The 'controlling mind' must be clearly identified and be expected to manage the risks that it creates. Ultimate responsibility for biosecurity rests with managers of a facility. A strong safety culture is essential for good biosecurity and all those who fund and operate high containment laboratories should ensure that this exists.**

78 ACDP, *The principles, design and operation of Containment Level 4 facilities*, p 22

79 Q 22; Sir Bill Callaghan, *A Review of the Regulatory Framework for Handling Animal Pathogens*, 13 December 2007, p 17

80 Sir Bill Callaghan, *A Review of the Regulatory Framework for Handling Animal Pathogens*, 13 December 2007, pp 16-17; Professor Brian Spratt and review team, *Independent Review of the safety of UK facilities handing foot-and-mouth disease virus*, August 2007, pp 49, 57

81 Q 91

82 Qq 270-271, 2, 87, Sir Bill Callaghan, *A Review of the Regulatory Framework for Handling Animal Pathogens*, 13 December 2007, p 16

83 ACDP, *The principles, design and operation of Containment Level 4 facilities*, p 22

84 Q 64; Ev 69, 76, 81-82, 97, 156; Sir Bill Callaghan, *A Review of the Regulatory Framework for Handling Animal Pathogens*, 13 December 2007, p15

85 Ev 82

44. **We support the role of Biological Safety Officers in enforcing biosecurity and recommend that the Government and the HSE in particular look at ways to support and reward this profession appropriately given the level of responsibility it holds, firstly by establishing a formal accreditation process.**

3 The HSE as a regulator

The HSE in its new role

45. Implementation of the changes proposed by Callaghan required a transitional period between January and April 2008 during which SAPO inspections in England for SAPO Group 4 pathogens were carried out by Defra and the HSE, and inspections of facilities using SAPO 2 and 3 pathogens were being carried out by the Veterinary Laboratories Agency (VLA) and the HSE. In Scotland, inspections are (and were) carried out by a Scottish Executive Veterinary Advisor, assisted by veterinarians from Animal Health (there are no SAPO 4 laboratories in Scotland). The HSE has now taken sole responsibility for all inspections of facilities handling dangerous pathogens across Great Britain as recommended by the Callaghan Review. Defra agreed to pay for this stage of the transition but the new regulatory framework will be partially paid for by recovering costs from inspected premises.[86] This will increase the cost of this research, and Lord McKenzie, Parliamentary Under Secretary of State at DWP, who has ministerial responsibility for the HSE accepted that this may prove to be a sensitive issue.[87]

46. Whilst the Callaghan review questioned the effectiveness of Defra inspections under SAPO, it found the HSE inspectorate to be "well trained and resourced to perform an inspection function efficiently and effectively,"[88] a view shared by others.[89] The HSE expects to inspect CL4 laboratories annually and CL3 laboratories every three years.[90] However, we received evidence that inspections are often infrequent unless problems are reported[91] and that the frequency should increase.[92] Concerns have also been expressed that the HSE may not have sufficient resources, especially with the new burden envisaged by the Callaghan Review, to inspect sufficiently,[93] although in fact the HSE has taken on fewer than ten laboratories with SAPO licences which they were not previously regulating via COSHH or GMO(CU).[94] Lord McKenzie assured us that he was confident that the HSE:

> will be sufficiently resourced to do the task … the three year review gives the HSE in aggregate something like a little bit better than flat cash in comparison to the 04 settlement. In the context of the DWP's minus five per cent real year-on-year you will see that we have tried to resource the HSE appropriately.[95]

86 Q 313

87 *Ibid.*

88 Sir Bill Callaghan, *A Review of the Regulatory Framework for Handling Animal Pathogens*, 13 December 2007, p 14

89 Ev 96, 156; Q 263

90 Q 113

91 Ev 98, 156

92 Ev 79

93 *New Scientist*, 'Animal lab mishaps go unreported', 1 January 2008, Ev 98, 103, 156

94 Q 99

95 Q 313

47. The HSE does not currently have the veterinary expertise necessary to administer the SAPO regulations, formerly undertaken by Defra veterinary officials. With the recruitment exercises underway, the HSE was confident that it would acquire sufficient expertise to take on its new, wider remit[96] and that the HSE could meet its targets for inspections with the new staff.[97] In addition, Dr Matthew Penrose told us that the HSE could refer to ACDP or the Scientific Advisory Committee on Genetic Modification for additional veterinary expertise,[98] and that the HSE and Defra are now working in close co-operation.[99]

48. **The Government must ensure that the HSE is sufficiently resourced to enforce the new regulatory framework properly. The shift of responsibility to the HSE for regulating animal pathogens following the Callaghan review should be accompanied by an appropriate increase in the resources the Government provides for this work. The HSE must ensure that it has the necessary veterinary expertise to allow it to regulate the use of animal pathogens and must co-operate with Defra to achieve this. The Government should review the additional resources needed to enable the HSE to deliver the new regulatory framework and publish this, accompanied by the rationale for the resource allocation.**

Engagement by the regulator

49. We agree with Professor Chris Thorns of the VLA and the Ministers with responsibility for Science and the HSE that it is critical that a good regulator engages with those building and operating high containment facilities before enforcement or intervention becomes necessary.[100] This should be a priority for the HSE as the regulator for the new unified framework and a task for which it will need to be resourced appropriately.

50. A particular issue arises over the culture of reporting accidents or near accidents to the regulator. The United States Government Accountability Office (USGAO) has pointed out that near misses and incidents could be going unreported[101] and suggested that an anonymous system might help to achieve better reporting.[102] It identified a number of "barriers to reporting accidents in high containment facilities":

> It has been suggested that there is a disincentive to report acquired infections and other mishaps at research institutions because of (1) negative publicity for the institution or (2) the scrutiny from a granting agency, which might result in the suspension of research or an adverse effect on future funding … In order to enhance reporting, barriers need to be identified and targeted strategies need to be applied to remove those barriers. It is also important that these incidents be analyzed so (1)

96 Q 43

97 Qq 114-115

98 Q 104

99 Q 89

100 Qq 185, 320, 324, 326, 330

101 USGAO, *High-containment biosafety laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, October 2007, pp 23-24

102 *Ibid,* p 16

> biosafety can be enhanced through shared learning from mistakes and (2) the public may be reassured that accidents are thoroughly examined and contained.[103]

We were reassured by the HSE's confidence that in the UK "compliance in the sector is good" and "the reporting mechanisms are good and well understood"[104] but we would caution that there is no room for complacency.

51. **We urge the HSE to engage as early as possible with those building and operating high containment facilities to avoid resorting to enforcement action. The HSE should review its procedures to consider how best to encourage reporting of incidents and near-misses.**

Information held by the regulator

52. A number of issues about the manner in which the HSE currently operates as a regulator arose during this inquiry, primarily as a result of the haphazard nature of the legislation it enforces. First, both the COSHH and GMO(CU) regulations require notifications of work on dangerous pathogens at "premises" without defining the term. The HSE receives notifications that refer to individual laboratories (the majority of notifications at CL4), sites (departments, locations and campuses) or the organisation (a university), but this is at the discretion of the notifier:

> Due to the flexible nature in which the law permits notifications to be made under both COSHH and GMO(CU) it can be difficult to capture intelligence on what particular work is being undertaken at a particular site. For example some employers choose to notify at the organisational level: once HSE have given permission for the work to proceed they are permitted to move this work between different sites (so long as those sites have been previously registered and meet the required standards) without notifying HSE. Other employers choose to notify at the site level: once HSE have given permission for the work to proceed these are not permitted to move this work between different sites without each new site notifying the work. This can apply to work at CL2 and CL3 but not CL4.[105]

The HSE can use its systems "to give a fuller picture" of work carried out by an organisation but described this as "a resource intensive process". [106] Dr Paul Logan accepted that this should change in future:

> The political imperative appears to be that people want to know down to very specific levels and if that is the case I think it is quite easy for organisations to provide that information – i.e., this organisation is working on these organisms in these particular laboratories at this particular address.[107]

103 USGAO, *High-containment biosafety laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, October 2007, p 16

104 Q 116

105 Ev 161

106 *Ibid.*

107 Q 132

53. Secondly, whilst all new work under COSHH must be notified to the HSE, COSHH regulations were introduced in 2002 and are not retrospective. For organisations which began to use the pathogen prior to this date, the HSE relies on information gained through surveys and inspections. Even if, as Dr Penrose believes, "in practice" the HSE is aware of all those using dangerous pathogens,[108] this is not an ideal state of affairs. This should be addressed by the new regulatory framework.

54. Thirdly, that it is of paramount importance that the HSE build strong links with organisations who might need access to the information it holds on work using dangerous pathogens. This would include the emergency services who might attend an incident at premises handling dangerous pathogens and the security services if they suspect pathogenic material is being misused. In addition, the agencies who have responsibility for human and animal health should be informed so that they may best respond to outbreaks of disease and account for possible sources of disease in contingency planning. Where accidental release is involved, as at Pirbright, identifying the causative agent and its source at the earliest opportunity is vital. Dr Matthew Penrose of the HSE told us that such links do exist but he accepted that:

> I guess it is fair to say that your question about the Department of Health is something that we need to work on, in terms of improving our relationship with the Health Protection Agency. That is something we have identified and are working closely on.[109]

55. **We recommend that the new regulatory framework require the HSE to maintain records of work on dangerous pathogens at a more detailed level than is currently the case and introduce clear guidelines as to whether organisations notify the regulator at a laboratory, site or organisational level. The new framework should be retrospective and should compel all those working with dangerous pathogens to notify the regulator. We urge the HSE to build relationships with those that may require access to such information, such as the animal and public health authorities and security services.**

108 Qq 110-112

109 Q 109

4 Facilities and capacity

Current facilities

56. In Switzerland all approved projects using dangerous pathogens are listed in an online database which can be interrogated by the public.[110] In contrast, we found it difficult to get details of high containment laboratories in the UK, largely due to considerations of national security. In response to our call for evidence, the HSE co-ordinated an audit of records to produce a breakdown of the number of organisations and sites operating containment laboratories in the UK as shown in table 1. It was also able to provide details of the regulations under which laboratories were registered (table 2).

Table 1

	Organisation or site type			
Containment level	**Government**	**Private**	**Research Council**	**University**
2	**212**	**230**	**17**	**70**
3	**202**	**98**	**7**	**40**
4	**5**	**2**	**3**	**0**

Table 2

	Number of organisations in Great Britain			
Containment level	**COSHH and/or GMO(CU) regulated only**	**SAPO regulated only**	**HSE & SAPO combined**	**Total**
2	**494**	**7**	**28**	**529**
3	**323**	**5**	**19**	**347**
	Number of sites			
4	**1**	**2**	**7**	**10**

Source: Ev 52

Note: For CL2/CL3 data shows number of organisations. For CL4 data shows number of sites. Only the highest CL used is recorded.

57. Only ten sites in the UK work with CL4 pathogens and aside from two manufacturers of veterinary vaccines, all are Government-sponsored. However, these facilities vary in capacity and capability, ranging from single rooms to multiple suites of CL4 laboratories on a single site.[111] Whilst the HSE is still in the process of carrying out further work to determine the exact number of CL3 laboratories, it reported that these are more widely distributed amongst universities and research council institutes (around 350) and private companies (around 75). Some large universities and research institutes operate significant numbers of CL3 laboratories; for example, two universities run 84 between them. Finally, the NHS run 170 CL3 laboratories, primarily for diagnostic purposes.[112]

58. In addition to high containment laboratories designed for research or diagnostics, there are two High Security Disease Isolation Units designed for the care of suspected cases of

110 Ev 147

111 Ev 162

112 *Ibid.*

Viral Haemorrhagic Fevers such as Ebola or Lassa.[113] Dr John Stephenson of the HPA told us that the high containment hospital sites were at Coppetts Wood and under development at the Royal Victoria Infirmary site at Newcastle. The Coppetts Wood site, rather than a research lab, would be used, should a post-mortem need to be performed on a deceased individual at CL4.[114]

Quality of facilities

59. We have observed at first hand the extent to which the quality of facilities can vary,[115] even those designated CL4. Some of the UK's facilities are world-class; for example the state-of-the-art facilities at the DSTL, Porton Down. In contrast, we found other facilities, at IAH Pirbright and at the HPA in Porton Down, to be in need of significant investment given their age, and we address these sites specifically in Chapter 5 of this Report. Our observations were supported by many witnesses who highlighted the deterioration of such laboratories.[116] The SGM went as far as to describe the state of the UK's central large animal facilities as "deplorable".[117]

Capacity for high containment research in the UK

60. The UK requires both the capacity to carry out ongoing research and surveillance, and the capacity to deal with the unexpected in an outbreak or after the emergence of a new pathogen. A clearly defined system of surveillance must also be in operation. During this inquiry we found that because of the way in which containment facilities vary in size and capability, the sufficiency of the UK's current facilities was hard to determine. Opinions on capacity at level 4 varied. The Academy of Medical Sciences and the Institute of Biology/Biosciences Federation suggested that capacity was lacking[118] but the Institute of Safety in Technology in Research, VLA and the Biotechnology and Biological Sciences Research Council (BBSRC) believed that capacity was sufficient.[119] The Medical Research Council (MRC), HPA, Defra and VLA told us that they have enough capacity for their current needs.[120] However, Dr John Stephenson of the HPA emphasised that this was only the case "if all the facilities which we have in hand are capable of running at full capacity … but that is a very big 'if'."[121] The UK has a larger number of CL3 laboratories, and no problems of capacity were highlighted at this level, although the lack of detail available makes it impossible to be certain.

61. Whilst a number of facilities are able to handle animals at SAPO4, the UK does not currently possess a facility able to handle large animals infected with human ACDP4

113 Ev 162

114 Q 213

115 Ev 63, 77

116 Ev 68, 117, 156; Qq 168, 281

117 Ev 156

118 Ev 98, 114

119 Ev 63, 68, 101

120 Ev 92; Qq 204-208, 371

121 Q 205

pathogens or uncharacterised CL3 viruses.[122] There are few laboratories of this type in the world but Germany considers the capability important enough to have included it in the redevelopment of the Friedrich Löeffler Institute on the Island of Reims.[123] In the UK, Defra held discussions about the inclusion of such a facility as part of the redevelopment project at Pirbright[124] but Professor Martin Shirley, Director of the IAH told us that it was not included on the basis of cost,[125] particularly the "very high recurrent running costs needed to maintain the physical, intellectual and technical competency."[126]

62. Ian Pearson MP, the Minister of State for Science and Innovation told us that ultimately "it is for the experts to come to conclusions about whether a large animal facility … is needed."[127] The BBSRC did not believe there to be a research need for such a facility at Pirbright.[128] Defra convened a meeting in March 2005 to discuss the need for an provision of such a facility in the UK.[129] A subsequent HSE survey of facilities indicated that:

> A number of animal facilities however, routinely operate at SAPO4 and ACDP3 and these provide a potential route for upgrading to ACDP 4. Subject to a cost/ benefit analysis an alternative strategy would be the new build of a dedicated facility for handling large animals at ACDP4 for managing zoonotic agents.[130]

63. Professor Chris Thorns of the VLA told us "nobody has come to me yet to say that we need large animal Category 4 facilities." He considered that such a facility is not necessary for the UK and stressed the need to "consider facilities in Europe and elsewhere".[131] However, he admitted that he was not aware of a facility able to conduct post mortem examination of large animals infected with CL4 pathogens and suggested that such examinations would be done in the field. It is unclear what would happen if that pathogen infects large animals and is classified as an ACDP4 pathogen that infects humans. This point was emphasised by Sir Leszek Borysiewicz, Chief Executive of the MRC, who told us that "where there is a possibility of transmission between species, particularly to the operator – then there is a need for such a Category 4 facility."[132]

Co-ordination and oversight of capacity

64. It is vital that the UK maintains the ability to undertake high containment science to counter the threat from infectious disease. Estimating the necessary capacity and capabilities to maintain ongoing research and diagnostics and then to provide surge capacity in the event of a disease outbreak is a difficult task. Any surplus of provision

122 Ev 101, 165

123 http://www.fli.bund.de/9+M52087573ab0.html

124 Q 34, Ev 165, 166; Notes of meeting to discuss Pirbright laboratory, 13 December 2004 (not printed).

125 Qq 294-296

126 Ev 166

127 Qq 360-361

128 Notes of meeting to discuss Pirbright laboratory, 13 December 2004 (not printed).

129 Ev 166

130 HSE paper on UK capability (not printed); see paragraph 73 below.

131 Qq 211, 216; see also paragraph 70.

132 Q 217

should be avoided, considering the high cost of running high containment facilities and issues of biosecurity. These factors make it important that there is adequate oversight and co-ordination of capacity. However, no comprehensive, cross-Government attempt has yet been made to determine what capabilities are required for the future and no organisation is charged with keeping track of current facilities.

65. From evidence submitted to the inquiry it appears that co-ordination of resources in high containment science is lacking. We have concluded that various Government departments sponsor high containment facilities in silos without reference to each other, and Rt Hon Lord Rooker, Minister of State for sustainable food and farming and animal health, Defra underlined this by telling us that:

> When you look at your own laboratories you clearly are responsible as the department, as the minister, to make sure of the operation of the laboratory as well as the focus on the finance and the actual research contracts as well as the other issues relative to biosecurity, but that does not therefore cover across Government.[133]

66. We were particularly struck when visiting Porton Down that the MOD redeveloped the high containment facilities at DSTL without co-ordination with the HPA whose facilities are within sight and in need of significant capital investment.[134] In addition, as we discuss in detail below, the redevelopment of IAH Pirbright is continuing whilst the future of the IAH, and animal health in general are still uncertain. We received evidence of spare capacity at DSTL Porton Down[135] and elsewhere at CL3, with the HSE informing us that they "often see laboratories that are under-utilised." [136] This suggests that more strategic planning may be needed. However, the HSE was unwilling to share information about spare capacity with other organisations to prevent needless facilities being built.[137] Dr Paul Logan considered that "I do not think it is the job of the regulator … to be looking at having an overview as to whether there is sufficient capacity."[138]

67. At an informal level there are arrangements between organisations about how facilities might be used. Dr Nick Coulson of Defra told us that facilities would be shared on an informal basis if the need arose:

> we do need to look with these very expensive facilities at how we get the best use out of them for the UK … the community does work together and talk to each other and the indications we have had from those discussions with people who own other facilities are that they would make them available.[139]

HPA and VLA co-operate in relation to influenza[140] and both are members of Interlab Forum, "a collaborative agreement between six Public Sector Research Establishments".[141]

133 Q 305

134 See below, para 119

135 Q 33

136 Ev 77; Q151

137 Qq 157-159

138 Q 151

139 Qq 148-150

140 Q 210

Whilst it is encouraging that facilities would probably be available if need arose, we do not believe that current arrangements are as clear and as formalised as they should be.

68. Beyond co-ordination, we also heard calls for an "overarching national strategy" to consider the future capacity for work on dangerous pathogens (BBSRC)[142] and a "UK-wide strategic review" (VLA).[143] At the moment, as Dr Nick Coulson of Defra told us, "there is not somebody with that strategic ability to take control at the moment," although an *ad hoc* group was convened by the deputy chief veterinary officer to look at the redevelopment of Pirbright.[144]

69. In the USA, the USGAO concluded that no single government agency has oversight of the provision of containment laboratories, indicating that a similar lack of oversight is an issue internationally.[145] We do not believe the lack of strategic oversight to be acceptable.

International co-ordination

70. There is clearly an international dimension to the provision of containment facilities. As well as training scientists from around the world,[146] UK laboratories such as those at the VLA, HPA and IAH are international centres of excellence, acting as world reference or European reference laboratories.[147] Given the costs of high containment research, we believe there to be greater potential for shared-use of facilities on a European basis, than is currently the case. For example, as we have noted, Professor Chris Thorns of the VLA suggested that this might be possible in the case of ACDP4 large animal facilities.[148]

The Griffin review of CL4 facilities

71. The MRC has recently commissioned the HPA to undertake a review of the provision of CL4 facilities in the UK, chaired by Professor Griffin, head of the ACDP.[149] BBSRC and Defra have since expressed an interest in the review, with BBSRC, MRC and HPA currently committed to fund it, although arrangements are not finalised. The Department of Health, Defra, MRC, BBSRC and HPA are represented on the steering committee which will agree the terms of reference and oversee the process. Those organisations represented on the steering committee will receive the final report which is scheduled for October 2008.

72. The draft terms of reference of the Review are as follows:

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141 http://www.interlabforum.co.uk/

142 Ev 107

143 Ev 63

144 Qq 152-154

145 USGAO, *High-containment biosafety laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, October 2007, pp 13-14

146 See chapter 6

147 Ev 53

148 Q 211

149 Ev 91, 95, 164, 167; Qq 205, 309, 329

- To obtain, and keep secure, a definitive list of all ACDP CL4 or SAPO4 facilities currently in operation across the UK, their location, capacity and capability in terms of the type work they support;
- To obtain information on the life expectancy and plans for refurbishment/new build of these existing facilities, to identify organisations which have an interest in using or providing ACDP CL4/SAPO4 facilities in the future and which may be planning their construction;
- To undertake a strategic horizon scanning programme in order to identify scientific and technology drivers that will define future needs and access requirements, in terms of capacity, technologies, safety, security and regulation, over a 10–20 year period. This will also consider the scope and constraints for introducing flexibility and sharing of the facilities available;
- To consider possible exemplars in Europe and North America particularly with respect to trends in likely physical infrastructure (suited versus cabinet line laboratories), location (urban versus remote sites) and security requirements;
- To identify the manpower and skills requirements for specialist personnel employed in ACDP CL4/SAPO4 facilities and all aspects (including costs) of the reaccreditation of both staff and facilities;
- To identify opportunities for collaboration and synergy to optimise effective and efficient provision, and value for money, in delivering UK high level containment needs for research and public health protection; and
- To submit a review report to the sponsors within eight months. [150]

Previous reviews of capacity

73. As described above, Defra previously convened a workshop to "to form a view on the need for an ACDP CL4 facility" for handling large animals once this was identified as a gap in the UK's capabilities. HSE subsequently reviewed the potential to convert existing facilities to be able to carry out work on large animals and sent a draft report to the Defra Chief Scientific Adviser.[151] When asked by ourselves Defra were unable to locate a finalised copy of this report and the Department appears not to have taken any further action on this issue.[152]

Improving co-ordination and oversight of high containment laboratories

74. **The Government should know the location, capacity and capability of all high containment laboratories in the UK. We accept that individual agencies are obliged to ensure they possess sufficient facilities for their own needs. However, given the costs of**

150 Ev 167

151 Ev 166, 169

152 Ev 169

building and maintaining high containment laboratories, efficient use of facilities is essential.

75. **While we commend the MRC for instigating the review of CL4 facilities currently underway under the chairmanship of Professor Griffin, we are disappointed that having started the process of identifying gaps in the UK's provision of high containment facilities, Defra did not act to address these. We believe it to be more appropriate that the Government lead a review of CL4 facilities than the MRC, given that the scope of those represented on the steering committee is somewhat wider than the MRC.**

76. **We recommend that the Government form a standing inter-agency body responsible for the strategic planning and co-ordination of containment level 4 facilities. Its members would include representatives of the Research Councils and Government departments that sponsor high containment facilities.**

77. **We recommend that within a year this inter-agency body undertake a detailed audit of the CL4 facilities currently available in the UK to determine capacity and capability, drawing on Professor Griffin's review. Capacity at CL3 should be assessed subsequently.**

78. **We recommend that the inter-agency body regularly review the capacity available for research at high containment and that it be consulted during redevelopment or building projects to look strategically at the need for new facilities, the potential for their shared use and whether particular capabilities should be included to provide what the UK requires. Early considerations should include the provision of post mortem facilities and facilities to handle large animals at ACDP4. It should also consider plans for the best use of high containment facilities during disease outbreaks.**

79. **We recommend that where possible, co-operation take place at a European and international level to promote burden-sharing and to investigate whether some facilities could be provided and shared at a European level where this is practicable.**

80. **We recommend that every two years the Government present to Parliament a report outlining the UK's readiness in the face of the threat posed by dangerous pathogens. This should include an analysis of the capacity and capability for research at high containment, set out the contingency plans for unexpected outbreaks of disease or the emergence of novel pathogens and how UK facilities will be used following such an event and include an updated long-term strategy for research and surveillance, accounting for climate change and other factors affecting the pathogens threatening the UK.**

Ministerial oversight

81. We asked the Ministers who appeared before us whether they had ever met on the issue of biosafety or biosecurity. They had not.[153] Lord Rooker from Defra told us "you are

153 Q 312

asking a question: who is in charge nationally of biosecurity? Frankly, you cannot get an answer to that."[154]

82. **We are disturbed that Ministers have not met to discuss the issue of biosecurity, especially given that no organisation or Government department has oversight in this area or responsibility for planning for future requirements, for example in the areas of surge capacity and anti-terrorist provision. We do not accept the view held by Lord Rooker that it is satisfactory for no Minister to have overall responsibility for biosecurity. We recommend that in view of the cross-cutting nature of these issues, the Government establish a ministerial group to meet periodically to discuss issues of biosecurity. A single Minister, for example the Minister for Science and Innovation, should take responsibility for co-ordinating biosecurity and the provision of high containment laboratories and should act to convene this ministerial group and the inter-agency body we have recommended be set up.**

Ownership of high containment laboratories by universities

83. In the UK no university runs a CL4 laboratory[155] (see table 1) but this is not the case elsewhere in the world, for example in the USA[156] or in Germany (in Marburg). We understand that a UK university has expressed an intention to develop a CL4 laboratory.[157] Dr Paul Logan of the HSE cited their reasoning as being that:

> getting access to level four capacity when they want it is quite difficult. For example, you can book time and you may get bumped from that if something happens, if there is an outbreak somewhere. The other argument is that they do not see any reason why level four should be uniquely in the hands of government rather than universities.[158]

84. None of our witnesses expressed objection in principle to a university running a CL4 laboratory, with Michael Stephens of the Institute of Safety in Technology and Research (ISTR) stating that:

> so long as they have the initial funding and the continued funding to keep the facility up to scratch, so long as the appropriate risk assessments are done, so long as the appropriate management controls are in place, there should be no reason why not.[159]

Ian Pearson MP agreed that there was no reason "to believe that universities are any less reliable than a government institute when it comes to running containment level four facilities."[160]

154 Q 304

155 Ev 52, 77

156 USGAO, *High-containment biosafety laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, October 2007, p 9

157 Qq 167, 220

158 Q 167

159 Q 293

160 Q 367

85. One significant barrier to such an application to run a CL4 laboratory could be the availability of sufficient long-term funding to maintain such a facility safely. Professor Robin Weiss, President of the SGM, told us that:

> in practice Category 4 is such a big investment that one university going it alone without conferring with other agencies or universities would have to have a very serious long term guaranteed investment to do so.[161]

86. An alternative is to provide CL4 facilities at centralised sites where they could be used as a 'science hotel' by university staff. Given the economies of scale involved, some witnesses argued that this would be more resource efficient and flexible.[162] This option was also preferred by Professor Griffin, Chair of ACDP who, when asked whether universities should operate CL4 facilities, told us that:

> I do not think any university should do now … If it is possible to share facilities, then that is very cost-effective ... I think universities should be encouraged to share.[163]

87. If such a system were to be in place, the universities must be assured of reliable access to these facilities. An example of such a shared resource is the Diamond Light Source, funded by the Science and Technology Facilities Council and the Wellcome Trust, where beamtime is allocated via a peer review process and is free at the point of use to academic users.[164] Similar systems operate at the Central Laser Facility[165] and ISIS,[166] also at the Rutherford Appleton Laboratory near Oxford.

88. **CL4 facilities are expensive to run and larger facilities benefit from economy of scale. We recommend that the body designated to co-ordinate CL4 capacity in the UK look at mechanisms by which spare capacity at existing facilities can be made reliably available to university researchers wishing to work at CL4, rather than allowing an unnecessary proliferation of facilities. Nevertheless, so long as sufficient resources are available to build, run and maintain a CL4 laboratory in the long-term to the required high standards, we have no objection in principle to universities operating these facilities.**

Location of facilities

89. Currently, all of the UK's ten CL4 facilities are located in the south of England, although CL3 facilities are widely distributed.[167] Some CL4 facilities, such as IAH Pirbright and the laboratories at Porton Down, are situated in relatively isolated locations but this is not the case for all. A number of CL4 laboratories exist in large cities around the world, including three in London which have been in operation for some time.[168] Germany is

161 Q 293

162 Ev 77, 103, 156; Q 368

163 Q 41

164 http://www.diamond.ac.uk/AboutDiamond/CompanyInfo/Funding

165 http://www.clf.rl.ac.uk/Access/LSFforms.htm

166 http://www.isis.rl.ac.uk/applying/index.htm

167 Ev 65, 77, 114, 162

168 Q 163

currently building new high containment laboratories for human pathogens at the Robert Koch Institute in Berlin,[169] and the Minister for Science and Innovation told us that "there are more than a dozen cities around the world where containment level four facilities do operate. I am not aware that there are any security or biosecurity issues as a result of those."[170]

90. Whilst CL4 facilities may already exist elsewhere in large cities, the question must be whether these are ideal locations for future developments. For example, the provision of additional biosecurity was the primary reason for the movement in the early 20th century of the Friedrich Löeffler Institute in Germany onto the Isle of Reims. Modern biorisk management strategies mean that isolated or island locations are not essential for high containment laboratories but location is still a consideration. In the USA, for example, there has been controversy over the possibility that the Department for Homeland Security will move FMDV research from its current location on Plum Island, off Long Island in New York, to a mainland location. The USGAO has concluded that evidence is lacking that such research can be done safely on the mainland. It cites the outbreak at Pirbright as the best evidence that that an island location is preferable since it can help prevent spread of the virus should an accidental release occur.[171] In addition, in Boston in the USA, there has recently been controversy over the location of a CL4 laboratory in the city and the adequacy of the analyses of worst case scenarios and alternative locations.[172]

91. These issues have acquired resonance in the UK with the announcement in December 2007 by the MRC, Cancer Research UK, the Wellcome Trust and University College London of their intention to establish the UK Centre for Medical Research and Innovation (UKCMRI), next to the British Library and St Pancras station in central London. Work carried out at the MRC's National Institute for Medical Research (NIMR) will move to the new site as determined by a scientific planning committee chaired by Sir Paul Nurse, President of Rockefeller University, New York. [173] At present the NIMR runs the only MRC-owned CL4 laboratory,[174] but whether this work will move to the UKCMRI is undecided. Sir Leszek Borysiewicz, the MRC Chief Executive told us that

> we have not put in a specific proposal in this regard. We are awaiting the considerations of a scientific committee to determine whether that science is actually necessary on that site and obviously before going further full security and other requirements would have to be considered. It is very important that we are not pre-judging the need or otherwise of such a facility as I made clear on a previous occasion.[175]

169 Press Notice, *Robert Koch Institute*, 4 December 2007. www.rki.de/cln_048/nn_753518/DE/Content/Service/Presse/Pressemitteilungen/2007/21__2007.html?__nnn=true

170 Q 365

171 *High–Containment Biosafety Laboratories, DHS Lacks Evidence to Conclude That Foot-and-Mouth Disease Research Can Be Done Safely on the U.S. Mainland*, United States Government Accountability Office, May 2008, p4-5.

172 Q 33, National Research Council, Committee on Technical Input on the National Institutes of Health's Draft Supplementary Risk Assessments and Site Suitability Analyses for the National Emerging Infectious Diseases Laboratory, Boston University, November 2007

173 http://www.mrc.ac.uk/NewsViewsAndEvents/News/MRC004253

174 Ev 92

175 Q 219

The UKCMRI project has also precipitated the Griffin review of CL4 facilities described earlier.

92. The idea of locating a CL4 laboratory at the UKCMRI has generated significant concern in the area and in the media.[176] Professor Griffin sympathised, when asked about locating CL4 laboratories in urban areas:

> I would try to avoid it, to be quite frank … because of the danger of spills or breakdown of facilities; because of what would happen if there was a very major leak, and if that leak was perhaps even terrorism-related, to the general population.[177]

He later qualified this by telling us that:

> Whilst I stated that I would wish to avoid situating a containment level 4 facility in a major conurbation, I would like to make it clear that decisions of that nature are informed by multi-factorial risk assessments in which scientific benefits are viewed in the context of potential risks.[178]

93. As the regulator, the HSE is content that it would be safe to have a CL4 laboratory operating in London "as long as it was designed, operated, maintained and run properly".[179] Professor Chris Thorns of the VLA concurred, telling us that:

> the location of Category 3 and Category 4 laboratories is part of an overall risk assessment. It is one important component. There are other equally important components which include availability of scientific and support expertise, the availability of maintenance staff, the closeness to emergency services and other support teams and communication links … Personally I do not have a problem with a Category 4 facility sited in a fairly highly densely population provided the risk assessments are transparent and have been carried out properly.[180]

94. We heard general agreement that consulting the HSE at an early stage was advisable when building new CL3 and Cl4 facilities.[181] Dr Paul Logan of the HSE told us that its inspectors "are consulted about plans for level four facilities. For level three facilities we encourage people to approach HSE … At the moment we would have the powers to stop the level four facility if we thought it was not going to be able to operate safely."[182] Lord McKenzie told us that he did not believe that the HSE's approval should necessarily be required for a proposed high containment laboratory.[183] However, there is an argument that the HSE should be required to approve an application to build a CL3 or CL4

176 Terror fears over disease laboratory at King's Cross, *The Evening Standard*, 23 April 2008, p 24; Coming soon?: A medical research lab is planned for the heart of London. Is it safe to house a facility dealing with deadly diseases in a large urban population? *The Guardian*, 22 April 2008, p 1 Education

177 Qq 39-40

178 Ev 164

179 Q 172

180 Q 218

181 Qq 288, 290, 326, 330

182 Qq 165-166

183 Q 366

laboratory early in the planning process to ensure that it is likely to meet the required standards, preventing the possible waste of resources.

95. **We consider that there is no reason in principle why CL4 laboratories should not be built in urban areas, provided that the correct risk assessment is undertaken and biorisk is managed appropriately. As each case will be unique, we recommend that such applications be treated on an individual basis.**

96. **We recommend that the HSE be a statutory consultee in any planning application for a CL3 or CL4 laboratory.**

5 Resourcing

97. The funding of high containment laboratories can be considered in two parts: the capital costs provided to construct the laboratory and the ongoing maintenance costs. There are particular generic issues with maintenance which we discuss here, followed by a closer examination of specific redevelopment projects.

98. Internationally there has been a programme of building in this area including a significant expansion of high containment laboratories in the USA,[184] projects in Germany[185] and in Australia, where the Government has announced a Networked Biosecurity Framework with $25m funding to upgrade the Australian Animal Health Laboratory in Victoria and to invest in biosecurity infrastructure.[186]

99. Robert Osborne, Biological Safety Adviser at the University of Glasgow told us that at Glasgow and other UK universities CL3 facilities are often not built as a strategic investment but are funded "on a piece-meal project/grant basis … typically they are small, disparate and have been developed with extensive inefficiencies" and may consequently be "underused or non-operational due to funding changes."[187] Other witnesses told us that the grant-based funding system means that applications do not always truly estimate the cost of biosecurity and maintenance and Full Economic Costing has not been met with an increase in total funding, leaving facilities under-resourced.[188]

100. It is important to take into account the significant cost of maintaining high containment facilities to avoid breaches of biosecurity. Michael Stephens from the ISTR told us that:

> a Category 4 facility, for example, may occupy one per cent of the floor space of a laboratory building, it may actually eat up to ten per cent of the on-going maintenance and utility cost annually of the whole building and that is really quite substantial.[189]

Small facilities have high overheads and can be three times more expensive to run per m^2.[190]

101. A number of witnesses highlighted difficulty in harnessing funding for ongoing maintenance;[191] for example Professor Chris Thorns of the VLA told us that:

184 USGAO, *High-containment biosafety laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, October 2007, pp 8-14

185 www.rki.de/cln_048/nn_753518/DE/Content/Service/Presse/Pressemitteilungen/2007/21__2007.html?__nnn=true www.fli.bund.de/9+M52087573ab0.html

186 www.ncris.dest.gov.au/NR/rdonlyres/BDE9EA41-9C43-4931-BE78-2102CB23E394/14716/NCRISfactsheets_networked_biosecurity.pdf

187 Ev 77

188 Ev 97, 103

189 Q 280

190 Ev 103, 156

191 Ev 68, 98

> these facilities cost an awful lot to run and maintain and often organisations like ourselves are given the capital investment but then everybody forgets the extra money needed to run these facilities.[192]

Professor Griffin described how in academia "we have to beg and scrape and get money for routine maintenance".[193] As a result of paying for necessary maintenance, money is diverted from science.[194] This problem is not restricted to the UK. The USGAO has discovered that in some cases the National Institute for Allergy and Infectious Diseases funded the construction of facilities but not their ongoing maintenance. Given the proliferation of high containment facilities in the USA, the issue may be a difficult long-term question to resolve.[195]

102. The importance of maintaining high containment laboratories was underlined by the leak of FMDV in 2007 where Professor Brian Spratt highlighted the role played by a lack of funding for maintenance at Pirbright :

> The poor state of the IAH laboratories, and the effluent pipes, indicates that adequate funding has not been available to ensure the highest standards of safety for the work on FMDV carried out at this ageing facility … There had been concern for several years that the effluent pipes were old and needed replacing but, after much discussion between IAH, Merial and Defra, money had not been made available.[196]

Government ministers did not accept this, however. Lord Rooker, Defra, told us that there was "no way the previous under-investment could account for the poor biosecurity at the site," and Ian Pearson, MP, DIUS, concurred: "What I would not accept is that the problems that occurred at Pirbright were as a result of under-investment … if the problems of the drains had been known, they would clearly have been dealt with."[197] We find Professor Spratt's conclusions more persuasive than those of the Ministers in this regard.

103. **The costs to human or animal health and to the economy of a breach of biosecurity at a high containment laboratory are devastating, as seen at Pirbright in 2007. We urge all those who fund high containment research to consider more seriously the cost of maintaining and running high containment laboratories. All funders of high containment laboratories must ensure that long-term funding for running costs is provided, sustained and protected to ensure risk management can take place effectively. The Government has a particular responsibility in this regard. UK research laboratories should be maintained by their operators to a high, internationally acceptable standard.**

192 Q 200

193 Q 36

194 Qq 36, 201

195 USGAO, *High-containment biosafety laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, October 2007, pp8-16

196 Professor Brian Spratt and review team, *Independent Review of the safety of UK facilities handing foot-and-mouth disease virus*, August 2007, p5

197 Qq 337-339

Redevelopment projects

Pirbright and IAH

104. BBSRC acknowledge that the IAH in Pirbright has suffered from a lack of investment.[198] This was also the conclusion of the Spratt Review[199] and a BBSRC-commissioned report by Sir Keith Gull in 2002 which described the facilities at Pirbright as "shabby".[200] A redevelopment programme in collaboration with the VLA was agreed in 2005[201] with the laboratories to be commissioned in 2012.[202] Construction work has now started on the site and there is common agreement that the Pirbright redevelopment project must go ahead,[203] with the IAH director, Professor Martin Shirley describing it as "really, really, really important as a national facility".[204]

105. In 2003 the cost of the redevelopment was estimated at £121m but this has now been revised to £165m. According to the BBSRC, this was "partly due to redesigns and partly due to inflation."[205] Both BBSRC and VLA expressed concern that those funding the project should also consider the significant long-term running costs of the new facility.[206] The detail of how the increase in costs will be met has yet to be decided by those committed to fund the project (BBSSRC, Defra and the DIUS Large Facilities Capital Fund).[207] Ian Pearson MP told us that:

> Exactly what pockets some of the additional money comes out of will have to be decided between us but the project will go ahead. It will be a mixture of funding from Defra, the BBSRC and its own capital resources and it will be a mixture of funding from the large facilities capital fund. We are not in a position to say exactly what those levels will be at the moment.[208]

106. Ian Pearson MP informed us that the decision on the Large Facilities Capital Fund monies was likely to be made in May 2008,[209] but we were concerned by Defra's seeming reluctance to accept responsibility for the increased cost of the project. Lord Rooker told us:

> It is not a bottomless pit though in the sense that we have agreed what we will put in but we are not responsible … for every overrun, and this is why we have to get

198 Ev 108

199 Professor Brian Spratt and review team, *Independent Review of the safety of UK facilities handing foot-and-mouth disease virus*, August 2007, p 34

200 Sir Keith Gull, *Review of the Institute for Animal Health – Pirbright Laboratory*, July 2002, www.bbsrc.ac.uk/organisation/policies/reviews/operational/0207_iah_pirbright.pdf

201 Q 198

202 Ev 108

203 Qq 152, 245, 281, 336, 338

204 Q 245

205 Q 198

206 Qq 198, 200, 245

207 Ev 108; Q 198

208 Q 342

209 Q 343

control of building costs. We have put in the money that we have agreed over the last few years.[210]

107. **The Pirbright redevelopment is of considerable national importance. We recommend that as a matter of urgency DIUS (via the BBSRC and Large Facilities Capital Fund) and Defra settle how they are to share the cost of the Pirbright redevelopment project as it now stands. At the very least, the final settlement should be announced by the time the Government responds to this report.**

Future structures

108. The future of the Pirbright site has been considered afresh following the outbreak of FMDV in 2007. In his report on the handling of the outbreak Dr Iain Anderson suggested that Defra should take the lead in transforming IAH into a 'National Institute of Infectious Diseases', supported by funding from government and elsewhere and with links to universities. He also suggested creating an Independent Advisory Committee on Animal and Emerging Infectious Diseases to take a strategic view of animal health.[211] In his report on the future of the IAH, Sir John Beringer concluded that "the redeveloped Pirbright laboratory should be positioned as a new 'National Centre for Animal Viral Disease' and should be founded upon a joint BBSRC-Defra science strategy for animal health and welfare."[212] The report suggested that there is a need for a national research strategy to co-ordinate the funders of research in the area of animal health. It further suggested that this should be led by Defra, closely co-operating with BBSRC, and should function through the formation of a new funding body whose members would include the Chief Veterinary Officer (or their deputy) and BBSRC Chief Executive.[213]

109. As an "admittedly radical and longer-term solution," Sir John Beringer suggests a new national agency be formed for animal health and welfare with a ring-fenced or independent budget. This agency would take responsibility for animal health (from Defra), the VLA and the Pirbright site. The report suggests that this would make animal health "less vulnerable to budgetary fluctuations and border disputes between organisations".[214]

110. Chris Thorns of the VLA told us that the VLA supports a merger between VLA and IAH.[215] The Government is still considering its response to the Anderson and Beringer reports.[216]

111. **The future of the Pirbright site and IAH and the question of its merger with the VLA must be settled as a matter of priority and in any case by April 2009 in line with the Beringer report recommendation on the ownership and management of the site (see below). Whilst Pirbright is undergoing redevelopment, we urge the Government to**

210 Q 336

211 Dr Iain Anderson, *Foot and Mouth Disease 2007: A Review and Lessons Learned*, 11 March 2008, p 6

212 *Review of funding, governance and risk management at the IAH*, A report for BBSRC Council, Sir John Beringer, April 2008, p 16, www.bbsrc.ac.uk/organisation/policies/reviews/operational/0804_iah_governance.pdf

213 *Ibid*, p 27

214 *Ibid*, p 29

215 Q 201

216 Qq 344-345

use the opportunity to develop a long term plan for animal health, considering the recommendations of the Anderson and Beringer Reviews.

112. **The question of the creation of a national centre at Pirbright, a national research strategy for animal health with a new funding body and a new national agency for animal health arose late in our inquiry and does not fall strictly within our terms of reference. However, we recognise that it is an issue of great importance and we recommend that as a matter of urgency the Government produce a White Paper to clarify its strategy for the future of animal health and welfare in the UK, provision of containment laboratories for research and diagnostics and how these would be used in an outbreak.**

Core funding and clarity of governance

113. The Beringer Report was clear that any National Centre at Pirbright with statutory responsibilities should not be funded "primarily through the award of research grants and contracts" and that long-term core funding should be provided:

> We recommend that core funding for the new National Centre at Pirbright should be administered as a single stream with a planning horizon of at least five years. Core funding must include adequate provision for core staff, running costs, maintenance and renewal of infrastructure, so that safety and biosecurity needs are satisfied.[217]

The Minister for Science and Innovation, DIUS, agreed:

> Beringer talks about long term, core funding and core funding is the right distinction. It does not mean long term, total funding to the organisation ... The principle that long term, core funding needs to be provided to the organisation … is one that I would support and certainly I know the BBSRC does.[218]

114. Our predecessor, the Science and Technology Committee, published a report on Research Council Institutes in March 2007 which included an examination of the financial relationship between Defra, the BBSRC and the IAH. It expressed concern that:

> The financial difficulties which have been experienced for some time by certain BBSRC and NERC institutes [including IAH] indicate that not all stakeholders are prepared to acknowledge the part they have to play in ensuring the sustainability of this part of the research base.[219]

115. The Science and Technology Committee Report highlighted the part played by the Research Council Institute and Public Sector Research Establishment Sustainability Study, sponsored by DTI but now owned by DIUS. This Study recommended that if a Government Department contributes more than 15% of the turnover of a Research Council Institute, then the Permanent Secretary should be jointly accountable "for

217 *Review of funding, governance and risk management at the IAH*, A report for BBSRC Council, Sir John Beringer, April 2008

218 Q 347

219 House of Commons Science and Technology Committee, Fourth Report of Session 2006–07, *Research Council Institutes*, HC 68, para 48

developing joint scientific and investment strategies for their cross-boundary research interests."[220] However, speaking to us, Lord Rooker was categorical about Defra's position:

> That is an untenable proposition if that is the proposition that is still floating around. We do not accept that simply because we have to have the capacity to let contracts to a variety of institutions … If the implication is that therefore we fund without an outcome, as someone that does not own or control the site, when we have other funding requirements, that is a major, major policy change … I ask you then to look at the consequences of that for science and other laboratories in the country where the same kind of contract relationship applies. In recent months, I have visited HRI, John Innes, IGER and Rothampstead, all of which we fund and are vital. We do not fund core funding.[221]

116. Related to this is Sir John Beringer's further recommendation that clarification be provided over who owns and manages the site:

> BBSRC and Defra must agree long-term arrangements for its ownership and management. If there is no prospect of agreement by April 2009 the matter should be resolved by referral through DIUS and Defra to the Cabinet Office[222]… there must be a single owner.[223]

Lord Rooker accepted in this instance that "if Ministers cannot agree, this would go to Cabinet."[224]

117. **We support the provision of long-term core funding for the redeveloped laboratories at Pirbright. Whatever the future of the Pirbright site, we support Sir John Beringer's recommendation that by April 2009, Defra and BBSRC should settle the long-term ownership and management of the Pirbright site; otherwise the issue should be referred to the Cabinet Office for resolution.**

118. **The Government should set out clearly its policy on the provision of core funding to research institutes with reference to the Research Council Institute and Public Sector Research Establishment Sustainability Study.**

HPA

119. During the inquiry we visited Porton Down and saw for ourselves the need to redevelop the HPA facilities at Porton Down. HPA explained that:

> category IV laboratories and many of the ACDP Category III laboratories were built over 50 years ago and refurbishment and upgrading work is becoming increasing difficult. Consequently the HPA has begun discussions with DH about the long term

220 http://www.berr.gov.uk/files/file14578.pdf, Recommendation2

221 Qq 346, 350, 351

222 *Review of funding, governance and risk management at the IAH*, A report for BBSRC Council, Sir John Beringer, April 2008, p 20

223 *Ibid*, p 3

224 Q 355

strategic redevelopment of the Porton site which will involve the construction of new high containment laboratories.[225]

120. **It is not acceptable that scientists at HPA Porton Down are asked to work in such ageing facilities. We recommend that the Department of Health consider the redevelopment of the HPA's Porton Down site a priority. Any redevelopment could be viewed as an opportunity to look at the UK's likely future wider requirements for containment facilities.**

225 Ev 117

6 Staff working on dangerous pathogens

Supply of staff

121. The Government estimates that 250,000 scientists currently work with dangerous pathogens in the UK.[226] On our visits to high containment facilities, we were universally impressed by the staff we met, some of whom work under exacting conditions.

122. Shortages of trained staff in the area of infectious disease were identified by the Institute of Safety in Technology and Research (ISTR), the Institute of Biology/Biosciences Federation[227] and the Society for General Microbiology (SGM) which highlighted that:

> There is a danger that the UK is gradually losing expertise to investigate and handle certain dangerous pathogens through previous lack of interest and lack of adequate funding, both in the medical and in the veterinary fields.[228]

Particular shortages have been highlighted in the area of CL4-trained staff in both medical and veterinary science.[229] Dr John Stephenson of the HPA expressed some doubt that his agency had sufficient CL4 expertise, with only three or four fully trained staff currently able to operate at this level,[230] despite the assertion by the Minister of State for Public Health, the Rt Hon. Dawn Primarolo MP, that there was no shortage at the HPA.[231] Both the HPA and the VLA are currently expanding their pool of CL4 trained staff, the latter in preparation for the opening of the new facility at Pirbright,[232] although both are confident that they have sufficient staff trained at CL3.[233]

123. Shortages of Biological Safety Officers (BSOs), trained managers[234] and researchers in the fields of medical entomology[235] and crop pathology[236] were also identified in evidence. It is vital that there are sufficient trained personnel to respond to outbreaks of infectious disease and we were not convinced that this is currently the case. For example, Professor Martin Shirley of IAH told us that there was a shortage of expertise to deal with an outbreak of bluetongue.[237] In addition to the staff operating containment facilities, concern has been expressed that there is a "lack of UK based specialist containment architects and engineers".[238]

226 Ev 51

227 Ev 68, 98

228 Ev 157

229 Qq 225, 227, 228; Ev 98

230 Q 225

231 Q 379

232 Ev 64; Qq 225-226,

233 Qq 225-226

234 Q 227; Ev 93

235 Q 285

236 Ev 107

237 Qq 284-285

238 Ev 68

124. **The specialist field of high containment biology is critical to the national interest of the UK. We recommend that, through the inter-agency body we have recommended be set up, the Government review the retention of staff and the incentives available for those working in this area to ensure that supply is sufficient for current and future needs.**

Training

125. The VLA describe the availability of trained staff as an "essential component" of capacity to carry out work at high containment.[239] The regulatory framework is confused in this area. For example, employers have a general requirement under Health and Safety law to provide adequate training, GMO(CU) regulations require specified training to be undertaken and COSHH regulations set out guidelines for the content of training.[240] Dr Matthew Penrose of the HSE told us that:

> The regulatory requirement is that it is left to individual organisations and sites as to how they want to train their staff … In the university setting there is not that legal requirement for all staff to be trained to a common level.[241]

126. We found that the provision of training in biorisk management and the handling of pathogens is not well co-ordinated, At present individual organisations are responsible for providing training and thus approaches vary. This is also the situation internationally.[242] Organisations run their own training schemes[243] which may not be readily transferable. ISTR told us that provision at a local level allows for a significant variation in the quality of training and perpetuates local practice, whether or not this is ideal.[244] However, we were told by organisations representing scientists that there is no evidence of a widespread failure to train staff adequately.[245] Dr Matthew Penrose of the HSE told us that "in practice we find that organisations do train their staff."[246]

127. Both laboratory managers and BSOs have a key role in biorisk management and require tailored training, especially since at present they are often responsible for training other staff in the laboratory. We heard support for a formalisation of their training[247] as is in progress in Switzerland.[248]

128. Some formal training courses for staff at various levels do exist. For example, the MRC runs a course for BSOs while both HPA and MRC run courses for those working in

239 Ev 64

240 Ev 58

241 Q 142

242 Ev 125, 128, 134, 136, 139, 145, 148

243 Ev 64, 69, 71, 73, 80, 98, 104, 115; Qq 44, 142

244 Ev 69

245 Ev 98, 115, 157

246 Q 142

247 Ev 82, 91

248 Ev 148

Containment Laboratories.[249] HPA is planning a purpose-built training facility at the Porton Down site which will be able to train up to CL4.[250] The ISTR is currently developing an accreditation programme for training providers,[251] and there is collaboration between the MRC and ISTR on the future of training programmes for biosafety professionals.[252] The ISTR and Robert Osborne, Biological Safety Adviser at the University of Glasgow expressed support for these initiatives and their extension.[253]

129. The development of standardised training regimes would be one way to ensure a uniform, high standard of staff training and would in addition give high containment work a more professional status.[254] Professor Griffin told us that Medical Laboratory Scientific Officers carrying out diagnostics in containment laboratories in the NHS have a structured training and accreditation programme.[255] Introduction of a similar scheme for all those handling dangerous pathogens could provide reassurance to employers that a basic level of competence has been reached. Conversely, given that those running a facility have ultimate responsibility for safety and training, some might prefer to continue to train individuals from scratch, to their own satisfaction. We heard strong support across the board (scientists, the HSE, funding bodies and Government Agencies) for a transferable certification of competence for working in high containment laboratories.[256] However, a number of witnesses were adamant that any certificate could not be relied upon completely and that certified training programmes should be minimalist, providing a baseline to be built upon with 'on the job' training using specific pathogens under local conditions.[257] Sir Leszek Borysiewicz, Chief Executive of the MRC, told us:

> we must not overlook … where the primacy of the responsibility for the safety of the individuals actually participating and working in such an environment actually resides … if I were running a Category 3 facility I do not care how many bits of paperwork a technician or a member of staff actually has, until they prove to me they are competent and are not endangering themselves or others I will not sign off that individual to actually operate in that sector.[258]

130. Unlike in other countries, undergraduate and masters programmes in the UK rarely include training in biosafety and biosecurity.[259] Sir Bill Callaghan told us that:

> there was an HSE commissioned report some years ago which recommended that health and safety should feature in undergraduate courses … we did not get as far as

249 Ev 66, 78, 93, 119; Qq 46, 223
http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/WTX041321.pdf

250 Q 223

251 Q 144; Ev 69

252 Q 221; Ev 78, 91

253 Ev 69, 78

254 Q 297

255 Q 46

256 Qq 45, 146, 297; Ev 70

257 Qq 44-45, 65-69, 78, 221-223, 297-298

258 Q 221

259 Ev 69; Q 59

> we would have liked because ultimately the responsibility for courses lies with the academic institution.[260]

The introduction of such content received support, including from the Minister for Science.[261]

131. **We recommend that the Government co-ordinate the funding and development of training schemes for those working with dangerous pathogens, building on schemes currently in existence. These should provide certification that a minimum level of competency has been reached and should be designed as a base from which staff can be further trained locally in the safe use of specific pathogens in a particular laboratory. Training programmes should be tailored to the needs of laboratory staff, principal investigators or BSOs whose training needs differ.**

132. **We recommend that DIUS engage with the higher education sector to ensure that undergraduate and masters programmes in relevant subjects include instruction in biorisk management.**

Vetting of staff

133. Laboratories working with dangerous pathogens are potential targets for those wishing to acquire pathogenic material or training in its handling for malicious purposes. Recognising the threat, in April 2005 the Association of Chief Police Officers and the Home Office published a guide to 'Personnel Security Standards for Laboratories' and circulated it to laboratories subject to Part 7 and Schedule 5 of ATCSA. However, security clearance for scientists working with dangerous pathogens is still not harmonised in the UK and for Home and EU staff or students security-vetting is not always a prerequisite for work with dangerous pathogens.[262]

134. Security procedures for laboratories differ according to containment level:

> CL 4 laboratories are subject to extensive security measures with extremely limited access. All staff granted access must undergo security clearance.
>
> CL 3 laboratories are subject to security measures required by ATCSA and receive bespoke advice regarding staff security checking.
>
> CL 2 laboratories are provided with bespoke advice regarding physical and personnel security by Counter-Terrorism Security Advisers.[263]

135. It is standard practice in Government-run laboratories that staff are security-vetted using Government vetting programmes. The HPA security-vet all those working at ACDP4 to SC level[264] and the VLA subjects all scientific staff working at or above CL3 to

260 Q 60

261 Qq 59, 380; Ev 123, 133; http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/WTX041321.pdf

262 Ev 69

263 Ev 57

264 Ev 119

counterterrorism checks, insisting that visitors are accompanied or undergo training and security-checking on the same basis as their staff.[265] Outside Government agencies, for example in universities, Research Council Institutes and the private sector, standards of security-vetting vary.[266] On our visit to Pirbright we were informed that IAH, despite undertaking contract work for Government departments, use a professional, private vetting agency for all staff working at CL4 because the institute does not have access to Government vetting schemes. We can see no reason why the ownership and governance of a laboratory should alter the necessity of reliable security-vetting and are concerned by the apparent lack of standardisation in this area, given its importance to national security.

136. In other countries such as Germany, Japan, Canada and others security vetting is a matter for the institution.[267] In the USA any organisation using a 'select agent' must provide a list of those staff involved in the project. The FBI then conduct finger-printing and background checking for these staff.[268]

137. For vetting of overseas students, a new system, the Academic Technology Approval Scheme (ATAS), was introduced in November 2007, administered by the Foreign and Commonwealth Office. Non-EU nationals applying to study sensitive subjects must hold a valid ATAS certificate specific to a Higher Education Institution (HEI) and programme of study before applying for entry to the UK or for an extension of their stay. The rules apply to research students and those undertaking masters programmes in some subjects. ATAS replaced the Voluntary Vetting Scheme under which HEIs were able to refer students to the FCO for vetting and received a recommendation on the suitability of the student for the programme. This scheme was considered burdensome and provided only patchy coverage of HEIs since it was discretionary.[269] Both Universities UK and the Research Councils are satisfied that ATAS is operating successfully.[270] However, as a new scheme, ATAS has not been in operation through the peak period for student admissions and there are concerns that increases in throughput may impact on turnaround time.[271]

138. There was widespread agreement in the evidence that security procedures should not restrict international movement of staff as part of free academic exchange.[272] In addition, the SGM, IAH and Astrazeneca highlighted that UK laboratories play a key role in training personnel from developing countries who are subsequently instrumental in controlling diseases at source.[273] It is possible that security vetting will, to some extent, restrict the movement of staff but ideally the vetting system should not deter *bona fide* staff from studying and working in the UK.

265 Ev 64

266 Ev 64, 95, 97

267 Ev 125, 126, 129, 132, 134, 136, 145

268 Ev 139

269 Ev 62

270 Ev 94, 111

271 Ev 112

272 Ev 63, 69, 74, 104, 116, 124, 153
http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/WTX041321.pdf

273 Ev 105, 124, 153

139. **Security-vetting is intended to minimise the risks of deliberate misuse of dangerous pathogenic material. This risk exists regardless of the ownership and governance of a laboratory or the country of origin of researchers and other staff. We therefore recommend that the Government provide access to Government vetting programmes so that all those working with CL4 pathogens can be reliably security-vetted to a consistent, high standard.**

7 Conclusion

140. By introducing a new unified regulatory framework in the wake of the Pirbright outbreak, the Government's policy on biosecurity is moving in the right direction. It is now imperative that the resources to implement the new framework are put in place. The lack of co-ordination in the provision of high containment laboratories means that facilities may not be being provided in the most efficient way at present. To set up an inter-agency body to oversee the provision of high containment laboratories, as we have recommended in this Report, is the appropriate way forward. This will provide a forum in which to develop strategic oversight in the area of high containment research and to address issues such as funding for long-term maintenance and redevelopment projects on a cross-government and co-operative basis. The outbreak of FMDV at Pirbright highlights that in the long run, proper regulation, running and maintenance of high containment facilities is considerably cheaper than remedying a breach of biocontainment.

Conclusions and recommendations

Implementation of the Callaghan Review

1. We support the conclusions reached by Sir Bill Callaghan and believe that a single, unified regulatory framework for human and animal pathogens based on risk assessment is the appropriate step forward. We urge the Government to ensure that regulation of work on dangerous pathogens is simplified as far as is practicable with the minimum number of bodies involved, although it may be appropriate for some specialist areas such as counter-terrorist inspection to be administered separately in accordance with the common framework. The Government should co-operate with the devolved administrations to ensure that a similarly high standard of regulation occurs across the UK. (Paragraph 32)

2. We recommend that the new unified regulatory framework be a permissioning regime such that approval by the regulator should be required before work can start where an application for work at CL3 or CL4 has been submitted. (Paragraph 33)

Categorisation of pathogens and containment measures

3. We support a common set of containment measures for animal and human pathogens and urge ACDP, in drawing up these measures, to protect the principles of evidence-based risk assessment. They should consider the implications for the viability of important research if unnecessary containment measures are imposed. We expect ACDP to maintain its regular review of required containment measures and the classifications of pathogens under the new framework. (Paragraph 37)

Responsibility for biosecurity

4. There should be complete clarity over who is responsible for biosecurity, especially on a site of mixed ownership or sponsorship such as at Pirbright. The 'controlling mind' must be clearly identified and be expected to manage the risks that it creates. Ultimate responsibility for biosecurity rests with managers of a facility. A strong safety culture is essential for good biosecurity and all those who fund and operate high containment laboratories should ensure that this exists. (Paragraph 43)

5. We support the role of Biological Safety Officers in enforcing biosecurity and recommend that the Government and the HSE in particular look at ways to support and reward this profession appropriately given the level of responsibility it holds, firstly by establishing a formal accreditation process. (Paragraph 44)

The HSE in its new role

6. The Government must ensure that the HSE is sufficiently resourced to enforce the new regulatory framework properly. The shift of responsibility to the HSE for regulating animal pathogens following the Callaghan review should be accompanied by an appropriate increase in the resources the Government provides for this work. The HSE must ensure that it has the necessary veterinary expertise to allow it to

regulate the use of animal pathogens and must co-operate with Defra to achieve this. The Government should review the additional resources needed to enable the HSE to deliver the new regulatory framework and publish this, accompanied by the rationale for the resource allocation. (Paragraph 48)

Engagement by the regulator

7. We urge the HSE to engage as early as possible with those building and operating high containment facilities to avoid resorting to enforcement action. The HSE should review its procedures to consider how best to encourage reporting of incidents and near-misses. (Paragraph 51)

Information held by the regulator

8. We recommend that the new regulatory framework require the HSE to maintain records of work on dangerous pathogens at a more detailed level than is currently the case and introduce clear guidelines as to whether organisations notify the regulator at a laboratory, site or organisational level. The new framework should be retrospective and should compel all those working with dangerous pathogens to notify the regulator. We urge the HSE to build relationships with those that may require access to such information, such as the animal and public health authorities and security services. (Paragraph 55)

Improving co-ordination and oversight of high containment laboratories

9. The Government should know the location, capacity and capability of all high containment laboratories in the UK. We accept that individual agencies are obliged to ensure they possess sufficient facilities for their own needs. However, given the costs of building and maintaining high containment laboratories, efficient use of facilities is essential. (Paragraph 74)

10. While we commend the MRC for instigating the review of CL4 facilities currently underway under the chairmanship of Professor Griffin, we are disappointed that having started the process of identifying gaps in the UK's provision of high containment facilities, Defra did not act to address these. We believe it to be more appropriate that the Government lead a review of CL4 facilities than the MRC, given that the scope of those represented on the steering committee is somewhat wider than the MRC. (Paragraph 75)

11. We recommend that the Government form a standing inter-agency body responsible for the strategic planning and co-ordination of containment level 4 facilities. Its members would include representatives of the Research Councils and Government departments that sponsor high containment facilities. (Paragraph 76)

12. We recommend that within a year this inter-agency body undertake a detailed audit of the CL4 facilities currently available in the UK to determine capacity and capability, drawing on Professor Griffin's review. Capacity at CL3 should be assessed subsequently. (Paragraph 77)

13. We recommend that the inter-agency body regularly review the capacity available for research at high containment and that it be consulted during redevelopment or building projects to look strategically at the need for new facilities, the potential for their shared use and whether particular capabilities should be included to provide what the UK requires. Early considerations should include the provision of post mortem facilities and facilities to handle large animals at ACDP4. It should also consider plans for the best use of high containment facilities during disease outbreaks. (Paragraph 78)

14. We recommend that where possible, co-operation take place at a European and international level to promote burden-sharing and to investigate whether some facilities could be provided and shared at a European level where this is practicable. (Paragraph 79)

15. We recommend that every two years the Government present to Parliament a report outlining the UK's readiness in the face of the threat posed by dangerous pathogens. This should include an analysis of the capacity and capability for research at high containment, set out the contingency plans for unexpected outbreaks of disease or the emergence of novel pathogens and how UK facilities will be used following such an event and include an updated long-term strategy for research and surveillance, accounting for climate change and other factors affecting the pathogens threatening the UK. (Paragraph 80)

Ministerial oversight

16. We are disturbed that Ministers have not met to discuss the issue of biosecurity, especially given that no organisation or Government department has oversight in this area or responsibility for planning for future requirements, for example in the areas of surge capacity and anti-terrorist provision. We do not accept the view held by Lord Rooker that it is satisfactory for no Minister to have overall responsibility for biosecurity. We recommend that in view of the cross-cutting nature of these issues, the Government establish a ministerial group to meet periodically to discuss issues of biosecurity. A single Minister, for example the Minister for Science and Innovation, should take responsibility for co-ordinating biosecurity and the provision of high containment laboratories and should act to convene this ministerial group and the inter-agency body we have recommended be set up. (Paragraph 82)

Ownership of high containment laboratories by universities

17. CL4 facilities are expensive to run and larger facilities benefit from economy of scale. We recommend that the body designated to co-ordinate CL4 capacity in the UK look at mechanisms by which spare capacity at existing facilities can be made reliably available to university researchers wishing to work at CL4, rather than allowing an unnecessary proliferation of facilities. Nevertheless, so long as sufficient resources are available to build, run and maintain a CL4 laboratory in the long-term to the required high standards, we have no objection in principle to universities operating these facilities. (Paragraph 88)

Location of facilities

18. We consider that there is no reason in principle why CL4 laboratories should not be built in urban areas, provided that the correct risk assessment is undertaken and biorisk is managed appropriately. As each case will be unique, we recommend that such applications be treated on an individual basis. (Paragraph 95)

19. We recommend that the HSE be a statutory consultee in any planning application for a CL3 or CL4 laboratory. (Paragraph 96)

Funding of high containment laboratories

20. The costs to human or animal health and to the economy of a breach of biosecurity at a high containment laboratory are devastating, as seen at Pirbright in 2007. We urge all those who fund high containment research to consider more seriously the cost of maintaining and running high containment laboratories. All funders of high containment laboratories must ensure that long-term funding for running costs is provided, sustained and protected to ensure risk management can take place effectively. The Government has a particular responsibility in this regard. UK research laboratories should be maintained by their operators to a high, internationally acceptable standard. (Paragraph 103)

Pirbright redevelopment project

21. The Pirbright redevelopment is of considerable national importance. We recommend that as a matter of urgency DIUS (via the BBSRC and Large Facilities Capital Fund) and Defra settle how they are to share the cost of the Pirbright redevelopment project as it now stands. At the very least, the final settlement should be announced by the time the Government responds to this report. (Paragraph 107)

Future structures for animal health

22. The future of the Pirbright site and IAH and the question of its merger with the VLA must be settled as a matter of priority and in any case by April 2009 in line with the Beringer report recommendation on the ownership and management of the site (see below). Whilst Pirbright is undergoing redevelopment, we urge the Government to use the opportunity to develop a long term plan for animal health, considering the recommendations of the Anderson and Beringer Reviews. (Paragraph 111)

23. The question of the creation of a national centre at Pirbright, a national research strategy for animal health with a new funding body and a new national agency for animal health arose late in our inquiry and does not fall strictly within our terms of reference. However, we recognise that it is an issue of great importance and we recommend that as a matter of urgency the Government produce a White Paper to clarify its strategy for the future of animal health and welfare in the UK, provision of containment laboratories for research and diagnostics and how these would be used in an outbreak. (Paragraph 112)

Core funding and clarity of governance

24. We support the provision of long-term core funding for the redeveloped laboratories at Pirbright. Whatever the future of the Pirbright site, we support Sir John Beringer's recommendation that by April 2009, Defra and BBSRC should settle the long-term ownership and management of the Pirbright site; otherwise the issue should be referred to the Cabinet Office for resolution. (Paragraph 117)

25. The Government should set out clearly its policy on the provision of core funding to research institutes with reference to the Research Council Institute and Public Sector Research Establishment Sustainability Study. (Paragraph 118)

HPA

26. It is not acceptable that scientists at HPA Porton Down are asked to work in such ageing facilities. We recommend that the Department of Health consider the redevelopment of the HPA's Porton Down site a priority. Any redevelopment could be viewed as an opportunity to look at the UK's likely future wider requirements for containment facilities. (Paragraph 120)

Supply of staff

27. The specialist field of high containment biology is critical to the national interest of the UK. We recommend that, through the inter-agency body we have recommended be set up, the Government review the retention of staff and the incentives available for those working in this area to ensure that supply is sufficient for current and future needs. (Paragraph 124)

Training

28. We recommend that the Government co-ordinate the funding and development of training schemes for those working with dangerous pathogens, building on schemes currently in existence. These should provide certification that a minimum level of competency has been reached and should be designed as a base from which staff can be further trained locally in the safe use of specific pathogens in a particular laboratory. Training programmes should be tailored to the needs of laboratory staff, principal investigators or BSOs whose training needs differ. (Paragraph 131)

29. We recommend that DIUS engage with the higher education sector to ensure that undergraduate and masters programmes in relevant subjects include instruction in biorisk management. (Paragraph 132)

Vetting of staff

30. Security-vetting is intended to minimise the risks of deliberate misuse of dangerous pathogenic material. This risk exists regardless of the ownership and governance of a laboratory or the country of origin of researchers and other staff. We therefore recommend that the Government provide access to Government vetting

programmes so that all those working with CL4 pathogens can be reliably security-vetted to a consistent, high standard. (Paragraph 139)

Annex: Abbreviations

ACDP	Advisory Committee on Dangerous Pathogens
ATAS	Academic Technology Approval Scheme
ATCSA	Anti-terrorism Crime and Security Act 2001
BBSRC	Biotechnology and Biological Sciences Research Council
BSA	Biological Safety Adviser
BSO	Biological Safety Officer
FMDV	Foot and Mouth Disease Virus
CL	Containment level
COSHH	Control of Substances Hazardous to Health Regulations 2002
CTSA	Counter-Terrorism Security Adviser
Defra	Department for the Environment, Food and Rural Affairs
DSTL	Defence Scientific and Technical Laboratories
DIUS	Department for Innovation, Universities and Skills
FCO	Foreign and Commonwealth Office
GMO(CU)	Genetically Modified Organisms (Contained Use) Regulations 2000
HEI	Higher Education Institution
HPA	Health Protection Agency
HSE	Health and Safety Executive
IAH	Institute for Animal Health
ISTR	Institute of Safety in Technology and Research
MOD	Ministry of Defence
MRC	Medical Research Council
NaCTSO	National Counter-Terrorism Security Office
NIMR	National Institute for Medical Research
RCUK	Research Councils UK
SGM	Society for General Microbiology
SAPO	Specified Animal Pathogens Order 1998
UKCMRI	UK Centre for Medical Research and Innovation
USGAO	US Government Accountability Office
VLA	Veterinary Laboratories Agency

Formal Minutes

Monday 16 June 2008

Members present:

Mr Phil Willis, in the Chair

Mr Tim Boswell	Dr Brian Iddon
Dr Evan Harris	Ian Stewart

Draft Report (*Biosecurity in UK research laboratories*), proposed by the Chairman, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 140 read and agreed to.

Summary agreed to.

Annex agreed to.

Resolved, That the Report be the Sixth Report of the Committee to the House.

Ordered, That the Chairman make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

[Adjourned till Wednesday 18 June at 9.00am.

Witnesses

Monday 17 March 2008

Page

Sir Bill Callaghan, former chair of the Health and Safety Commission, Chairman of the review of the regulatory framework for handling animal pathogens, and **Professor George Griffin**, Chair of the Advisory Committee on Dangerous Pathogens — Ev 1

Dr Paul Logan, Principal Specialist Inspector, Specialised Industries Division, and **Dr Matthew Penrose**, Principal Specialist Inspector, Specialised Industries Division, Health and Safety Executive, **Dr Ruth Lysons**, Deputy Director, Food & Farming Group, and **Dr Nick Coulson**, Head of International Animal Health, Department for Environment, Food and Rural Affairs — Ev 9

Monday 31 March 2008

Professor Chris Thorns, Science Director, Veterinary Laboratories Agency, **Dr John Stephenson**, Director of Research and Development, Health Protection Agency, **Sir Leszek Borysiewicz**, Chief Executive, Medical Research Council, and **Mr Steve Visscher**, Chief Executive (interim), Biotechnology and Biological Sciences Research Council — Ev 20

Professor Martin Shirley, Director, Institute for Animal Health, **Professor Robin Weiss**, President, Society for General Microbiology, and **Mr Michael Stephens**, Institute of Safety in Technology and Research — Ev 28

Monday 21 April 2008

Rt Hon Dawn Primarolo MP, Minister of State, Department of Health, **Ian Pearson MP**, Minister of State, Department for Innovation, Universities and Skills, **Rt Hon Lord Rooker of Perry Bar**, Minister of State, Department for Environment, Food and Rural Affairs, and **Lord McKenzie of Luton**, Parliamentary Under Secretary of State, Department for Work and Pensions — Ev 36

List of written evidence

List of unprinted evidence

The following memoranda have been reported to the House, but to save printing costs they have not been printed and copies have been placed in the House of Commons Library, where they may be inspected by Members. Other copies are in the Parliamentary Archives, and are available to the public for inspection. Requests for inspection should be addressed to The Parliamentary Archives, Houses of Parliament, London SW1A 0PW (tel. 020 7219 3074). Opening hours are from 9.30 am to 5.00 pm on Mondays to Fridays.

- HSE and Defra Joint Workshop, Future requirements for large animal facilities for work with the most hazardous pathogens, March 2005, redacted minutes

- HSE and Defra, Large animal facilities for work with the most hazardous pathogens: The UK's Capability, October 2005 draft report

- Office of Science and Technology, Department for Environment, Food and Rural Affairs and Biotechnology and Biological Sciences Research Council, minutes of a meeting to discuss Pirbright laboratory, December 2004

List of Reports from the Committee during the current Parliament

The reference number of the Government's response to each Report is printed in brackets after the HC printing number.

Session 2007–08

First Report	UK Centre for Medical Research and Innovation	HC 185 (HC 459)
Second Report	The work and operation of the Copyright Tribunal	HC 245 (HC 637)
Third Report	Withdrawal of funding for equivalent or lower level qualifications (ELQs)	HC 187-I (HC 638)
Fourth Report	Science Budget Allocations	HC 215 (HC 639)
Fifth Report	Renewable electricity-generation technologies	HC 216-I
First Special Report	The Funding of Science and Discovery Centres: Government Response to the Eleventh Report from the Science and Technology Committee, Session 2006–07	HC 214
Second Special Report	The Last Report: Government Response to the Thirteenth Report from the Science and Technology Committee, Session 2006–07	HC 244
Fourth Special Report	Investigating the Oceans: Government Response to the Science and Technology Committee's Tenth Report of Session 2006-07	HC 506 [incorporating HC 469-i]